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Enforcement Report - Week of February 5, 2014

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Product Type	Product Description	Code Info	Classification	Reason for Recall	Recalling Firm
Biologics	Platelets Pheresis Leukocytes Reduced	GS23054	Class II	Blood product, which was labeled as leukoreduced, but was not tested to verify white blood cell count, was distributed.	Blood Bank Of San Bernardino and Riverside Counties
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	107228280 (2 units)	Class II	Blood products, which did not meet the minimum requirement for volume, were distributed.	Blood Systems, Inc.
Biologics	Red Blood Cells	GS45134	Class II	Blood product, collected in a manner that may have compromised the sterility of the unit, was distributed.	Blood Bank of San Bernardino and Riverside Counties
Biologics	Red Blood Cells Leukocytes Reduced	107979009	Class III	Blood product, for which the entire amount of additive solution was not added during manufacturing, was distributed.	Blood Systems, Inc.
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	107973991,107978084	Class III	Blood products, which may have been exposed to unacceptable storage temperatures, were distributed.	Blood Systems, Inc.
Biologics	Red Blood Cells Leukocytes Reduced	107968469	Class III	Blood products, which may have been exposed to unacceptable storage temperatures, were distributed.	Blood Systems, Inc.
Biologics	Platelets Pheresis Leukocytes Reduced	36FM47411	Class II	Blood product, which contained an insufficient plasma volume, was distributed.	The American National Red Cross South Carolina Region
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	107980629 (2 units)	Class II	Blood products, collected from a donor who was taking the medication Avodart, were distributed.	Blood Systems, Inc.
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	16LL76290	Class II	Blood products, collected from a donor for whom donor suitability was not adequately determined, were distributed.	American National Red Cross
Biologics	Red Blood Cells Leukocytes Reduced	036FY39361, 036FY39367, 036FY39369	Class II	Blood products, for which there was a discrepancy in the sample tubes for viral marker testing, were distributed.	American National Red Cross (The)
Biologics	Platelets Pheresis	17FE84919	Class III	Blood product, which may have reached an unacceptable temperature during storage, was distributed.	St Joseph'S Medical Ctr Blbank
	The Centricity Laboratory System is intended to be an information system designed to support the clinical and administrative activities associated with the provision and utilization of clinical				

Devices	laboratory services and facilities, e.g., the storing and delivering of analytical results. It is a specially designed data program application (software), which is supplied for installation in existing mainframe or decentralized computers or a computer network. This software system will not be the software directly used to run, steer, or control any specific laboratory analyzer or equipment. It is intended for use in laboratory facilities, including a central laboratory or in a multiple laboratory environment servicing satellite laboratories, reference laboratories, clinics, etc. Centricity Laboratory System is not intended for direct patient contact. The Centricity Laboratory System product is designed to facilitate the general clinical, anatomic pathology and cytology laboratory workflow such as order entry, results entry, instrument interfacing, results reporting and patient record retrieval. It integrates with other Hospital Information Systems (HIS) through HL7 interface by order entering and also report processing. The Centricity Laboratory System is intended to interface with various lab results. Centricity Laboratory System is intended to be used by laboratory technologists, technicians, analyst and other trained/site authorized system users	Software Versions: 3.3, 4.0, 4.1	Class III	GE Healthcare is aware of a potential safety issue associated with the use of GE Centricity Laboratory Core Lab calculated results in two scenarios. In Scenario 1: Calculated results greater than 6 digits plus a decimal are reported as 0 instead of TOO BIG when significant figures are not defined for the item. In Scenario 2: Calculated results greater than 6 digits plus a decimal are truncated if significant figures are defined.	GE Healthcare It
Biologics	Bone	UBO0057420184; UBO0057420185; UBO0057560679; UBO0057560680; UBO0057850605; UBO0057850606; UBO0058550052; UBO0058550053; UBO0060520331; UBO0060520332; UBO0061290057; UBO0061290058; UBO0061630062; UBO0082020034; UBO0082020068; UBO0082020069; UBO0082020237; UBO0082020238; UBO0082020352; UBO0082020370; UBO0082020371; UBO0082740060; UBO0082740061; UBO0082740064; UBO0082740065; UBO0082950526; UBO0083160032; UBO0083160033; UBO0085100022; UBO0085920072; UBO0085920072; UBO0087380081; UBO0087430065; UBO0087800054;	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's	University of Miami Miller School of Medicine Tissue

		UBO0087800058; UBO0087890040; UBO0087890041; UBO0088540053; UBO0088540054; UBO0089140130; UBO0089200034; UBO0089200035; UBO0089310068; UBO0089310070; UBO0089540118; UBO0089540119; UBO0089650078; UBO0089650079; UBO0089720073; UBO0089720074; UBO0089720074; UBO0090050064; UBO0090460074; UBO0090710039; UBO0090720063; UBO0090720064; UBO0090720065; UBO0090720066; UBO0090810077; UBO0090810078; UBO0090880048; UBO0090980073; UBO0090980074; UBO0091060078; UBO0091370041; UBO0091410064; ... More		instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	Bank
Biologics	Bone	UBI0082020002; UBI0087020084; UBI0087020093; UBI0089290068; UBI0089290069; UBI0090560104; UBI0090560111; UBI0090730079; UBI0090730087; UBO0044660073; UBO0044660129; UBO0045350099; UBO0045580201; UBO0046310001; UBO0046310195; UBO0046830061; UBO0056670143; UBO0056670218; UBO0058270003; UBO0058550015; UBO0059900093; UBO0059900095; UBO0059900153; UBO0060520095; UBO0061290033; UBO0061630003; UBO0061630058; UBO0061640005; UBO0085490057; UBO0085490060; UBO0086790053; UBO0086790054; UBO0086790060; UBO0086790061; UBO0087000068; UBO0087000069; UBO0087000078; UBO0087000079; UBO0087240055; UBO0087240058; UBO0087240065; UBO0087240066; UBO0088080076; UBO0088080077; UBO0088080083; UBO0088080084; UBO0089190053; UBO0089190060; UBO0089310056; UBO0089310057; UBO0089310064; UBO0089310065; UBO0089500062; UBO0089500071; UBO0089560065;	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	University of Miami Miller School of Medicine Tissue Bank

		UBO0089560066; UBO0089940080; UBO0091070037; UBO0091070038; UBO0091070044; UBO0091070045; UBO0091800058; UBO0091800066; UBO0091800067; UBO0093260037; ... More			
Biologics	Bone	082360041; UBO0082360044; UBO0082740008; UBO0082740009; UBO0082740011; UBO0082740013; UBO0082740014; UBO0082740015; UBO0082740016; UBO0082740018; UBO0082740019; UBO0082740020; UBO0082740021; UBO0082820001; UBO0082820002; UBO0082820003; UBO0082820004; UBO0082820006; UBO0082820009; UBO0082820010; UBO0082820011; UBO0083120001; UBO0083120002; UBO0083120009; UBO0083120010; UBO0083120012; UBO0083120014; UBO0083120015; UBO0083120016; UBO0083120017; UBO0083120018; UBO0083120019; UBO0085490049; UBO0085490050; UBO0085490051; UBO0085490052; UBO0085490053; UBO0085490054; UBO0085490055; UBO0085490056; UBO0085490061; UBO0085920058; UBO0085920059; UBO0085920060; UBO0085920061; UBO0085920063; UBO0085920064; UBO0085920065; UBO0085920066; UBO0085920067; UBO0085920074; UBO0085920075; UBO0085920076; UBO0085920077; UBO0085920078; UBO0085920079; UBO0085920080; UBO0086490047; UBO0086490048; UBO0086490051; UBO0086490052; UBO0086490053; UBO0086490054; UBO0086490055; UBO0086490056; UBO0086640041; UBO0086640042; ... More	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	University of Miami Miller School of Medicine Tissue Bank
		USK0044570001; USK0044570002; USK0044570003; USK0044570004; USK0044570005; USK0044570006; USK0057690769; USK0057690770;			

Biologics	Bone	USK0057690771; USK0057690772; USK0057690773; USK0057690774; USK0057690775; USK0057690776; USK0057690777; USK0057690778; USK0057690779; USK0057690780; USK0057690781; USK0057690782; USK0057690783; USK0057690784; USK0057690785; USK0057690786; USK0057690787; USK0057690788; USK0057690789; USK0057690790; USK0057690791; USK0081870630; USK0081870631; USK0081870632; USK0081870633; USK0081870634; USK0081870635; USK0081870636; USK0081870637; USK0081870638; USK0081870639; USK0081870640; USK0081870641; USK0081870642; USK0081870643; USK0081870644; USK0082020618; USK0082020619; USK0082020620; USK0082020621; USK0082020622; USK0082020623; USK0082020624; USK0082020625; USK0082020626; USK0082020627; USK0087320035; USK0087320036; USK0087320037; USK0087320038; USK0087320039; USK0087320040; USK0087320041; USK0087320042; USK0087320043; USK0087380036; USK0087380037; USK0087380038; ... More	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	University of Miami Miller School of Medicine Tissue Bank
Biologics	Bone	UDM0057690797; UDM0057690798; UDM0057690799; UDM0087290053; UDM0087290054; UDM0087290055; UDM0087290056; UDM0087290057; UDM0087290058; UDM0087320044; UDM0087320045; UDM0087320046; UDM0087320047; UDM0087360025; UDM0087360026; UDM0087360027; UDM0087360028; UDM0087360029; UDM0087800071; UDM0087800072; UDM0087800073; UDM0087800074; UDM0087800075; UDM0087800076; UDM0089200029; UDM0089200030; UDM0089540144; UDM0089540145; UDM0089540146;	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce	University of Miami Miller School of Medicine Tissue Bank

		UDM0089540147; UDM0089540148; UDM0089570035; UDM0089570036; UDM0089570037; UDM0089570038; UDM0089570039; UDM0089940333; UDM0089940334; UDM0089940335; UDM0089940336; UDM0089940337; UDM0089940338; UDM0090030075; UDM0090030076; UDM0090320241; UDM0090320242; UDM0090470125; UDM0090470126; UDM0090470128; UDM0090470129; UDM0091060096; UDM0092130072; UDM0092130073.		the risk of transmission of relevant communicable disease agents or diseases, were distributed.	
Biologics	Bone	UPO0090560006; UPO0090810029; UPO0091060004; UPO0091070030.	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	University of Miami Miller School of Medicine Tissue Bank
Biologics	Bone	010150351; UBO0010150352; UBO0010150353; UBO0010150354; UBO0010150355; UBO0010150356; UBO0010150357; UBO0010150358; UBO0010150359; UBO0010150360; UBO0010150361; UBO0010150362; UBO0010150363; UBO0010150364; UBO0010150365; UBO0010150366; UBO0010150367; UBO0010150368; UBO0010150369; UBO0010150370; UBO0010150371; UBO0010150372; UBO0010150373; UBO0010150374; UBO0010150375; UBO0010150376; UBO0010150377; UBO0010150378; UBO0010150379; UBO0010150380; UBO0010150381; UBO0010150382; UBO0010150383; UBO0010150384; UBO0010150385; UBO0010150386; UBO0010150387; UBO0010150388; UBO0010150389; UBO0010150390; UBO0010150391; UBO0010150392; UBO0010150393; UBO0010150394; UBO0010150395; UBO0010150396; UBO0010150397; UBO0010150398; UBO0010150399;	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	University of Miami Miller School of Medicine Tissue Bank

		UBO0010150400; UBO0010150401; UBO0010150402; UBO0010150403; UBO0010150404; UBO0010150405; UBO0010150406; UBO0010150407; UBO0010150408; UBO0010150409; UBO0010150410; UBO0010150411; UBO0010150412; UBO0010150414; UBO0010150415; UBO0010150416; UBO0010150417; ... More			
Biologics	Bone	UBO0094860174	Class III	Human tissue allografts, whose donor eligibilities were not determined by using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases, were distributed.	University of Miami Miller School of Medicine Tissue Bank
Drugs	HCG (Lyophilized) Stock # 21714, 5000 IUnits-5 mL vial, Compounded by NuVision Pharmacy Dallas, TX 75244	Lot #s: N06252012@6 Exp 6/25/13; N01042013@15 Exp 1/29/14; N05072012@3 Exp 2/1/15	Class I	Lack of Assurance of Sterility: The recall is being initiated due to a lack of sterility assurance and concerns associated with the quality control processes identified during an FDA inspection.	NuVision Pharmacy, Inc.
Drugs	Sermorelin/GHRP-6, 3 mg/3 mg, 5 mL vial, Stock # 21740, Compounded by NuVision Pharmacy, Dallas, TX 75244	Lot #:N10172012@11, Exp 10/17/2013	Class I	Lack of Assurance of Sterility: The recall is being initiated due to a lack of sterility assurance and concerns associated with the quality control processes identified during an FDA inspection.	NuVision Pharmacy, Inc.
Devices	Codman Certas Programmable Valve In Line Valve Only Product Code: 82-8800 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	Lot Codes: CLNCB1 CMBBP1 CMBCPN CMCBWG CMCC2V CMDCN8 CMDDJN CMGB8H CMJCL8 CMJCPW CMKB21 CMMCGR CMNBFB CMNBZJ CMNC8T CMNCYL CMPB4V CNCCPF CNDBCW CNDBRH CNDCJ2 CNFCK7 CNGBG0 CNGBK2 CNHCKH CNHCZN CNJBW5 CNJBWZ CNJC38 CNJC4K CNJCD3 CNJCFR CNJCMN CNKBWP CNKCC8 CNKCL3 CNLBR6 CNLCL3 CNLCW3 CNNCWF CNPB1R CNPBRH CNPCLR CPBC96 CPBCCR CPBCRV CPCBG9 CPCCMK CPDBYC CPDC07 CPDCC7 CNBBCV CNCB6W CNGBRY CNHB95 CNNDCK CNPB1T CNPBML CPBB3G CPCBG8 CPCCBH CPCCM1 CPCCMZ CPFBKP	Class II	Codman Certas Programmable Valves used for hydrocephalus may not operate properly	Codman & Shurtleff, Inc.
	Codman Certas Programmable Valve In Line Valve with Catheter and Accessories Product Code: 82-8801 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of	Lot Codes: CMBBP2 CMCBLG CMDBHG CMFBB8 CMHDFW CMJCPY CMLBLW CMLCKP CMMBCY CMMC3F CMNBFC CMNCDW CMPB96 CNCCLK CNJBW0 CNJC4B CNJC4W CNKBWN CNKCL1 CNLBR3 CNLBZF CNMDM1 CNNCPL CNNDH4 CNPBRM CPBBGP CPBC97 CPBCRW CPCBHB CPCCMP CPDBYF CPBCVD CPDBYD CPDBM1			

Devices	CSF (cerebrospinal fluid) for the management of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	CMBCB2 CMCBLH CMDBHF CMGBL5 CMJCMC CMLBLY CMNBZK CNDCV1 CNHC8N CNKB41 CNLBR5 CNMB2Z CNMDNN CNNCWG CNPB1Y CNPCLT CPBCRY CPFBK1 CLPCM9 CMBBB2 CMBBB3 CMDBHD CMDCN7 CMDDJT CMFBNK CMFBNL CMNBZG CNDCP3 CNGBK5 CNHCZP CNJB1F CNJC4R CNJCMP CNKB0Y CNLCL0 CNMCYY CNMDNJ CNNDH0 CNPBRK CNPCLW CPBBGR CPCCBC CPCCML CPDCC2	Class II	Codman Certas Programmable Valves used for hydrocephalus may not operate properly	Codman & Shurtleff, Inc.
Devices	Codman Certas Programmable Valve In Line Valve with Unitized BactiSeal Catheter and Accessories Product Code: 82-8803 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	Lot Codes: CLPCM9 CMBBB2 CMBBB3 CMDBHD CMDCN7 CMDDJT CMFBNK CMFBNL CMNBZG CNDCP3 CNGBK5 CNHCZP CNJB1F CNJC4R CNJCMP CNKB0Y CNLCL0 CNMCYY CNMDNJ CNNDH0 CNPBRK CNPCLW CPBBGR CPCCBC CPCCML CPDCC2	Class II	Codman Certas Programmable Valves used for hydrocephalus may not operate properly	Codman & Shurtleff, Inc.
Devices	Codman Certas Programmable Valve In Line Valve only with SiphonGuard Device Product Code: 82-8804 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	Lot Codes: CNMCDP CNMDM2 CNMDNG CNFCVJ CNHB96 CNHC8L CNHCZM CNHCZT CNJBWW CNJBWY CNJCFP CNJCG9 CNKB0R CNKBTR CNKCL0 CNKCL2 CNLBR2 CNLBZD CNMCDV CNMDM3 CNNCWC CNPB1W CNPBRJ CNPCLP CPBB39 CPBBGN CPBC98 CPBCKR CPBCKT CPCBG7 CPCCBG CPDBYH CPDC09 CPDCC4 CNBB13 CNCB6L CNDB8B CNDBVZ CNDCM9 CNHC8J CNHCKG CNJC39 CNJC4H CNJC4J CNJCB0 CNDCM8 CNKB42 CNFCVH CNHCZH CNJB98 CNLCW4 CNMBFK CNMCDW CNMDNH CNNCWH CNNDH2 CNNDH3 CNPB1V CPBB3H CPBCR0 CPCBG6 CPCCBD CPCCBF CPDBYG CPDCC6 CMMB1L CMBC2W CMDBHB CMDDJP CMDDJR CMKB22 CMLCKR CMMCR5 CMNBFD CMNCVP CMNCYM CMPB95 CMPBMD CNBBCZ CNCB4R CNCB61 CNMCDR CPCCMW	Class II	Codman Certas Programmable Valves used for hydrocephalus may not operate properly	Codman & Shurtleff, Inc.
Devices	Codman Certas Programmable Valve In Line Valve with SiphonGuard Device, Catheter and Accessories Product Code: 82-8805 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of	Lot Codes: CMBC2Y CMDCN9 CMJC48 CMLC6D CNCCLB CNCCZ4 CNDBRG CNDCNB CNHC8M CNJC4P CNKCL4 CNLCL1 CNMB8Y CNMDM0 CNNDHY CNPCLZ	Class II	Codman Certas Programmable Valves used for hydrocephalus may not	Codman & Shurtleff, Inc.

	hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	CPBC99 CPCC27 CPDBYJ CMNBFF CMNCDY CNCB6M CPBCRZ CPDCKL		operate properly	
Devices	Codman Certas Programmable Valve In Line Valve with Siphonguard, Unitized Catheter and Accessories Product Code: 82-8806 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	Lot Codes: CMJCMD CMBC2Z CMDB7C CMJC49 CMBCPR CMCC2T CMDBHC CMLBLZ CMMB14 CNDBCY CNDCV2 CNJCFT CNKBH6 CNLB57 CNMDNL CNNCWD CNPB1Z CPBB3J CPBDBB CPCCM0 CPDBYK	Class II	Codman Certas Programmable Valves used for hydrocephalus may not operate properly	Codman & Shurtleff, Inc.
Devices	Codman Certas Programmable Valve In Line Valve with SiphonGuard Device, Unitized Bactiseal Catheter and Accessories Product Code: 82-8807 Product Usage: The CODMAN CERTAS Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular perssure drainage of CSF. The CODMAN CERTAS Therapy Management System (TMS) allows the non-invasive reading or adjustment of the valve setting.	Lot Codes: CLPCNB CMBCPT CMCC2W CMDB6L CMDDJV CMKB24 CMLCKN CMMC3H CMNBZH CNCB6N CNCCLJ CNCCZ3 CNDB8C CNDBRJ CNGBK4 CNHCZR CNJB1G CNJC4T CNJCMR CNKBZD CNLBVM CNLBZC CNMBFL CNNDH1 CNMBFM CNMDNK CNPBRL CNPCLV CPBBGT CNCCLH CNCCZ2 CNDB69 CNDCV0 CPBCR3 CPCBHC CPCBHD CPDCC3 CMMCGV CNBB11 CPBCR4 CPCCMN CPDBYL	Class II	Codman Certas Programmable Valves used for hydrocephalus may not operate properly	Codman & Shurtleff, Inc.
Devices	T3F, Free T3 Assay, REF/Catalog Number LKF31, Siemens Material Number (SMN) 10381626; an IVD Immunoassay kit for use with the IMMULITE/IMMULITE 1000 Analyzers --- Shipping or unit package: 100, 200, 500 and 600 test kits --- Origin: UK Siemens Healthcare Diagnostics Products Ltd. Llanberis, Gwynedd, LL55 4EL UK. For the quantitative measurement of Free T3 in serum, as an aid in the clinical assessment of thyroid status.	Lot Numbers 353, 354	Class II	Siemens Healthcare Diagnostics confirmed customer complaints regarding an increase in the number of euthyroid patients (those with normal function of the thyroid) demonstrating values above the recommended normal range as published in the Instructions For Use for the IMMULITE/IMMULITE 1000 and/or IMMULITE 2000/IMMULITE 2000 XPi for several lots of Free T3 kits. A positive bias in quality control results was also observed, but the values may remain within	Siemens Healthcare Diagnostics

				the established ranges.	
Devices	T3F, Free T3 Assay, REF/Catalog Number L2KF32 (200 tests), Siemens Material Number (SMN) 10381675, and REF/Catalog Number L2KF36 (600 Tests), SMN 10381682; an IVD Immunoassay kit for use with the IMMULITE 2000/IMMULITE 200 XPi Analyzers --- Origin: UK Siemens Healthcare Diagnostics Products Ltd. Llanberis, Gwynedd, LL55 4EL UK. For the quantitative measurement of Free T3 in serum, as an aid in the clinical assessment of thyroid status.	Lot Numbers 737, 738, 739, 740, 741, 742, 743	Class II	Siemens Healthcare Diagnostics confirmed customer complaints regarding an increase in the number of euthyroid patients (those with normal function of the thyroid) demonstrating values above the recommended normal range as published in the Instructions For Use for the IMMULITE/IMMULITE 1000 and/or IMMULITE 2000/IMMULITE 2000 XPi for several lots of Free T3 kits. A positive bias in quality control results was also observed, but the values may remain within the established ranges.	Siemens Healthcare Diagnostics
Devices	Brilliance iCT and Brilliance iCT SP These systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. May include signal analysis and display equipment, patient and equipment supports, components and accessories	Model # 728306 100016, 100018, 100019, 100020, 100021, 100022, 100023, 100024, 100025, 100028, 100031, 100032, 100037, 100038, 100039, 100040, 100042, 100043, 100044, 100045, 100046, 100047, 100048, 100049, 100050, 100051, 100052, 100053, 100054, 100055, 100056, 100057, 100058, 100059, 100060, 100061, 100062, 100063, 100064, 100065, 100066, 100067, 100068, 100069, 100070, 100071, 100072, ... More	Class II	An artifact that resembles thrombus may appear on the image.	Philips Medical Systems (Cleveland) Inc
Devices	Brilliance iCT, Brilliance 64 and Brilliance Big Bore The Brilliance iCT, Brilliance 64 and Brilliance Big Bore are Computed Tomography X-Ray Systems intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient, and equipment supports, components and accessories.	Brilliance iCT: Model Number 728311 and 728306, Serial Number: 100103, 100019, 100023, 100170, 200047, 200013 200005 and 100087. Brilliance 64: Model Number 728231 and 728326, Seial Number: 4003, 9745, 9875, 90135, 90169, 95414, 300003, 300004, 300005 and 300010. Brilliance CT Big Bore, Model Number: 728243, Serial Number: 7006, 7060, 7154, ... More	Class II	The DoseRight feature suggest a mAs based on the measured patient size, a reference size and a reference mAs. When scanning large children, the suggested mAs may be higher than clinicians would expect.	Philips Medical Systems (Cleveland) Inc
Devices	User Defined Method Flex Assignment/Siemens Dimension Vista 500 or Dimension Vista 1500 System with software version 3.5.1 or lower User Defined Method Flex Assignment/Siemens Dimension Vista 500 or Dimension Vista 1500 System is an in vitro diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids.	Material numbers 10284473, 10488224, 10444801, and 10444802.	Class II	When utilizing the Routine Inventory screen to enter a User Defined Method (EMPTY) Flex the system may assign the User Defined Method Flex to a different Flex that is currently in inventory on the system, and then use the incorrect Flex Cartridge to process the user defined method.	Siemens Healthcare Diagnostics, Inc.
Food	Bean Paste Bread, Net Wt. 420 g, product is packaged within a plastic bag with twelve (12) bags per carton.	lot no: 4400	Class III	LSG Food World Inc., has recalled Bread Filled with Jam and Bean Paste Bread due to a misbranded product label (lacks english translation).	Lsg Food World Inc

Food	Bread Filled with Jam, Net Wt. 420 g, product is packaged within a plastic bag with twelve (12) bags per carton.	lot no: 4400	Class III	LSG Food World Inc., has recalled Bread Filled with Jam and Bean Paste Bread due to a misbranded product label (lacks english translation).	Lsg Food World Inc
Food	Lam Sheng Kee Fu Zhou Vermicell, Net Wt. 4.4 LB (2000 g), product is packaged in plastic bag with twelve (12) bags per carton. UPC 6949682 803360; Manufactured by LAM SHENG KEE (HK) INTERNATIONAL LIMITED RM3. 8/F, YUEXIU BLDG., 160-174 LOCKHART ROAD, WAN CHAI HK; Distributed by: S&M INT'L INC 100 Pulaski Street, Bayonne, NJ 07002, Product of China.	Item no: 803360, Best Before 10/06/2014	Class III	LSG Food World Inc., has recalled Fu Zhou Vermicelli due to filth subject to Import Alert 02-02 and the product is misbranded in that it does not have English translation.	Lsg Food World Inc
Devices	Aquarius (TM) TEMPERATURE THERAPY, REF T650, Rx Only, Manufactured for DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849, Made in China. Physical Therapy.	Lot Numbers: 31480713, 31480721, 31968743, 31971619, 31990844, 32005711, 32018491, 32037764, 32118020, 32710832, 32736223, 33053264, 33105221, 33141176, 33164204, 33164407, 33276273, 33329911	Class II	The unit displays an error code of hose kinking when no hose kink is present; the unit fails to monitor the temperature of the water in the blanket as intended and controlling it through the automatic temperature control. This failure could result in temperature injuries to the treatment site; and there have been two reports of electric shock.	DeRoyal Industries Inc
Devices	DeRoyal (R) Aquarius Hot/Cold Therapy Combo Unit, w/ Knee/Shoulder Blanket NS, REF T652NS, Rx only, Manufacturer DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849. Physical Therapy.	Lot Numbers: 32871821, 32976471, 33105247	Class II	The unit displays an error code of hose kinking when no hose kink is present; the unit fails to monitor the temperature of the water in the blanket as intended and controlling it through the automatic temperature control. This failure could result in temperature injuries to the treatment site; and there have been two reports of electric shock.	DeRoyal Industries Inc
Devices	DeRoyal (R) Aquarius Hot/Cold Therapy Combo Unit, w/ Knee/Shoulder Blnkt NS, REF T653NS, Rx only, Manufacturer DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849. Physical Therapy.	Lot Numbers: 32901145, 33063999, 3132641, 3217556, 33276468, 33369411, 33412431, 33415413	Class II	The unit displays an error code of hose kinking when no hose kink is present; the unit fails to monitor the temperature of the water in the blanket as intended and controlling it through the automatic temperature control. This failure could result in temperature injuries to the treatment site; and there have been two reports of electric shock.	DeRoyal Industries Inc
Devices	DeRoyal (R) Aquarius Hot/Cold Therapy Combo Unit, w/ Knee Blanket w/ Straps NS, REF T654NS, Rx only, Manufacturer DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849. Physical Therapy.	Lot Numbers: 32871775, 32980891, 33132755, 33141184, 33217572, 33329945	Class II	The unit displays an error code of hose kinking when no hose kink is present; the unit fails to monitor the temperature of the water in the blanket as intended and controlling it through the automatic temperature control. This failure could result in temperature injuries to the treatment site; and there have been two reports of electric shock.	DeRoyal Industries Inc
	DeRoyal (R) Aquarius Hot/Cold Therapy Combo Unit, w/ Shoulder Blanket			The unit displays an error code of hose kinking when no hose kink is present; the unit fails to monitor the temperature of the water in the blanket as intended	

Devices	w/ Straps NS, REF T655NS, Rx only, Manufacturer DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849. Physical Therapy.	Lot Number: 32871812	Class II	and controlling it through the automatic temperature control. This failure could result in temperature injuries to the treatment site; and there have been two reports of electric shock.	DeRoyal Industries Inc
Devices	DeRoyal (R) Aquarius Hot/Cold Therapy Combo Unit, w/ Foot/Ankle Blanket NS, REF T656NS, Rx only, Manufacturer DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849. Physical Therapy.	Lot Numbers: 32901129, 32980912, 33015541, 33024746, 33105239	Class II	The unit displays an error code of hose kinking when no hose kink is present; the unit fails to monitor the temperature of the water in the blanket as intended and controlling it through the automatic temperature control. This failure could result in temperature injuries to the treatment site; and there have been two reports of electric shock.	DeRoyal Industries Inc
Drugs	Soliris (eculizumab) Concentrated Solution for Intravenous Infusion Only, 300 mg/30 mL (10 mg/mL), 30 mL Single-Use Vial, Rx only, Manufactured by: Alexion Pharmaceuticals, Inc., Cheshire, CT 06410, NDC 25682-001-01, UPC 3 25682-001-01 6.	Lot #: 10001-1, Exp 07/14; 10010A, Exp 10/15	Class I	Presence of Particulate Matter: Failed the appearance test for the presence of visible particles.	Alexion Pharmaceuticals, Inc.
Devices	Kimberly-Clark RadiOpaque Radiofrequency Cannula, Gauge 22, Length 100 mm, Active Tip 10 mm, Distributed in the US by Kimberly-Clark,Product code PMF22-100-10 The product is used to create lesions in nervous tissue when used with the Kimberly-Clark radiofrequency generator and probes.	Lot M3085K301 and M2327K301	Class II	Product may contain a cannula with an active tip length of only 5mm rather than 10mm as indicated on the label.	Kimberly-Clark Corporation
Drugs	Rhino 5 capsules(Spanish & English Labeling), 1 capsule per blister pack, Distributed by P&A Enterprise, Buena Park, CA 90621, English UPC 6 10708 10730 9, Spanish UPC 6 10708 10729 3.	Lot #: KWAKPMC03050517595701 9, Exp 12/16	Class I	Marketed Without An Approved NDA/ANDA: FDA analysis found Rhino 5 which is marketed as a dietary supplement to contain undeclared desmethyl carbondenafil and dapoxetine. Desmethyl carbondenafil is a phosphodiesterase (PDE)-5 inhibitors which is a class of drugs used to treat male erectile dysfunction, making this product an unapproved new drug. Dapoxetine is an active ingredient not approved by the FDA.	SS Wholesale Inc. dba Jobbers Wholesale
Drugs	MaXtremeZEN capsules, 1 capsule per blister pack, Distributed by: P&A Enterprise, Buena Park, CA 90621, UPC 6 10079 52468 2.	Lot #: JBP-L-1270-70, Exp 12/16	Class I	Marketed Without An Approved NDA/ANDA: FDA analysis found MaXtremeZEN which is marketed as a dietary supplement to contain undeclared desmethyl carbondenafil and dapoxetine. Desmethyl carbondenafil is a phosphodiesterase (PDE)-5 inhibitors which is a class of drugs used to treat male erectile dysfunction, making this product an unapproved new drug. Dapoxetine is an active ingredient not approved by the FDA.	SS Wholesale Inc. dba Jobbers Wholesale

Drugs	eXtenZone capsules, 1 capsule per blister pack, Distributed by: P.M.C. Company, Buena Park, CA 90621, UPC 6 89076 49126 6.	Lot #: KWAKPMC03050517, Exp 12/16	Class I	Marketed Without An Approved NDA/ANDA: FDA analysis found eXtenZone which is marketed as a dietary supplement to contain undeclared desmethyl carbondenafil and dapoxetine. Desmethyl carbondenafil is a phosphodiesterase (PDE)-5 inhibitors which is a class of drugs used to treat male erectile dysfunction, making this product an unapproved new drug. Dapoxetine is an active ingredient not approved by the FDA.	SS Wholesale Inc. dba Jobbers Wholesale
Food	Digestive, Enzyme Supplement, packaged 90 capsules per bottle, 135 capsules per bottle, or 270 capsules per bottle. They are sold under brand Enzyme Research Products or Empower Life.	Digestive (90 count): LOT #1206801, EXP 03/15 (means March 2015); Digestive (135 count): LOT # 1108103, EXP 03/14 (means March ... More	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	B-Complex with Enzymes, Vitamin/Enzyme Supplement. Packaged 60 vegetable capsules per bottle. They are sold under brand Enzyme Research Products.	LOT# 1224405, EXP 08/15 (means August 2015)	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	B-Complex Plus. They are sold under brand Enzyme Research Products	LOT# 1108001, EXP 03/14 (means March 2014)	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	Glucosamine, Chondroitin, MSM Plus, dietary supplement, 60 capsules per bottle. They are sold under brand Enzyme Research Products or Empower Life Vital Joints brand.	LOT# 1125804, EXP 09/14 (means September 2014); LOT# 1214301, EXP 05/15 (means May 2015); LOT# 1308601; EXP 03/16 (means March 2016);	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	Zinc Plus, Mineral/Enzyme supplement, 90 vegetable capsules per bottle. They are sold under brand Enzyme Research Products.	LOT# 1228603, EXP 10/15 (means October 2015); LOT# 1134004, EXP 12/14 (means December 2014);	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	Digestaze, dietary supplement, 90 vegetable capsules per bottle. They are sold under brand DESBIO	LOT# 1215904, EXP 06/14 (means June 2014).	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	Enzyme Formula, dietary supplement, 100 capsules or 250 capsules per bottles, sold unlabeled to Rich Distributing.	LOT# 1319603, EXP 07/15	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	XymoZyme, dietary supplement, packaged 60 capsules per bottte, 120 capsules per bottle, sold under brand ZYMOGEN.	60 count bottle: LOT# 1207301D, EXP 03/14 (means March 2014); LOT# 1221501D, EXP 08/14 (means August 2014); LOT# 1229205D, EXP 10/14 (means October 2014); 120 count bottle: LOT# 1207301H; EXP 03/14 (means March 2014); LOT# 1221501H, EXP 08/14 (means August 2014); LOT# 1229205H, EXP 10/14 (means October 2014);	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc

Food	Digest Ultra, dietary supplement, packaged 56 capsules per bottle or distributed in bulk, sold under brand YOR. Product distributed OUTSIDE the US has Spanish label.	LOT Numbers: 1207408; MFG -03/12; 1217703; MFG -06/12; 10190112; MFG -01/12; 10190112; MFG -01/12; 10190312; MFG-03/12; 10190313; MFG -03/13; 10191112; MFG -11/12; 20190313; EXP- 2/2015; 20190612; EXP- 06/14; 20191012; EXP -10/14; 1019A0811; EXP- 08/13 ;	Class II	Dietary supplement products are recalled because they were made from ingredient that was contaminated with Chloramphenicol.	Health Wright Products Inc
Food	California Girl canned Peach Halves in Juice, 6 cans per case. UPC 52391 72992	Code: 3700/01182 OCT.-08-2012 OCT.-08-2015	Class II	Atlapac Trading Co. is recalling California Girl canned Peach Halves because they were reported to be swollen.	Atlapac Trading Company Inc
Drugs	KETOCONAZOLE CREAM, 2%, 30 gram tube, Rx only, E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc., Melville, New York 11747, NDC 0168-0099-30, UPC 3 0168-0099-30 9.	Lot #: 495P, Exp 07/14	Class III	Failed Impurities/Degradation Specifications: Out-of-Specification degradant results.	Fougera Pharmaceuticals Inc.
Food	Shortbread Almond Crescent cookies sold under the Lambs Farm brand and packaged in a plastic bag with a net weight of 10 oz.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare milk, soy, and wheat allergens.	The Lambs Farm, Inc.
Food	Double Chocolate Butter Cookies sold under the Lambs Farm brand and packaged in a plastic bag with a net weight of 10 oz.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare milk and wheat allergens.	The Lambs Farm, Inc.
Food	Famous Butter Cookies sold under the Lambs Farm brand and packaged in a plastic bag with a net weight of 10 oz.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare milk and wheat allergens.	The Lambs Farm, Inc.
Food	Lemon Butter Cookies sold under the Lambs Farm brand and packaged in a plastic bag with a net weight of 10 oz.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare milk and wheat allergens.	The Lambs Farm, Inc.
Food	Snowball Cookies sold under the Lambs Farm brand and packaged in a white metal tin with a net weight of 1 lb.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare milk, soy, and wheat allergens.	The Lambs Farm, Inc.
Food	Cheerful Cookie Combo containing an assortment of Lemon Butter Cookies and Famous Butter Cookies sold under the Lambs Farm brand and packaged in a white metal tin with a net weight of 1 lb.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare milk and wheat allergens.	The Lambs Farm, Inc.
Food	Raspberry Swirl Bread loaf sold under the Lambs Farm brand and packaged in a plastic bag with a net weight of 8 oz. This product was only sold as a part of the Bread Trio gift box.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare soy allergens.	The Lambs Farm, Inc.
Food	Banana Nut Bread loaf sold under the Lambs Farm brand and packaged in a plastic bag with a net weight of 8 oz. This product was only sold as a part of the Bread Trio gift box.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare soy allergens.	The Lambs Farm, Inc.
	Blueberry Bread loaf sold under the Lambs Farm				

Food	brand and packaged in a plastic bag with a net weight of 8 oz. This product was only sold as a part of the Bread Trio gift box.	All batches coded with dates 7/1/2013 through 11/14/2013.	Class II	The labels do not declare soy allergens.	The Lambs Farm, Inc.
Biologics	Red Blood Cells Leukocytes Reduced	13C42347	Class II	Blood product, which was incorrectly labeled with respect to the red cell antigens, was distributed.	American National Red Cross Southeastern Michigan Region
Devices	GE Optima CT520 and Optima CT540 Computed Tomography (CT) systems. Intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.	Mfg Lot or Serial # System ID 00000311096HM2 561747CT2 00000317657HM5 859313TCCT 00000318100HM5 765447CDICT 00000320796HM6 317569CDINE 00000322703HM0 317846CDINCT 00000323060HM4 651294OPT 00000325273HM1 317890CDIS 00000325782HM1 317890CDIW 00000325783HM9 INSIGHTCT2013 00000326335HM7 Unknown 00000328883HM4 606573O540 00000330505HM9 972596CT540 00000331902HM7 651294OPT 00000333256HM6 Unknown 00000336763HM8 620384CT 00000337348HM7 850325OPT540 00000338324HM7 251275GHCTOP540 00000338344HM5 419ARROWCT 00000339268HM5 817465PORT 00000339269HM3 571367OP540 00000339708HM0 980212CT 00000340245HM0 ... More	Class II	There is an issue with the Manual Film Composer feature on some CT products. There is an opportunity, while following a specific workflow, to create a film image with one patient's images and another patient's name in the footer. This is also an issue when within Manual Film Composer, if a color image is selected for printing, another patient's black and white image appears in the preview screen and the color image cannot be printed.	GE Healthcare, LLC
Biologics	Red Blood Cells Leukocytes Reduced	W0423130405491	Class II	Blood products, which tested negative for West Nile Virus (WNV) using pooled testing, but were not tested for WNV by individual donor testing, were distributed.	Blood Systems, Inc
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	W042313040551D (2 units), W0423130405555 (2 units),	Class II	Blood products, which tested negative for West Nile Virus (WNV) using pooled testing, but were not tested for WNV by individual donor testing, were distributed.	Blood Systems, Inc
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	W041513030506I	Class III	Blood product, for which the additive solution was not added during manufacturing, was distributed.	Blood Systems, Inc. dba United Blood Services Texas
	Mercuroclear Antiseptic Anesthetic First Aid Helps prevent infection and relieves pain and itching of minor cuts, scrapes, burns and insect bites. Aqueous solution. Active Ingredients Benzalkonium chloride 0.13% - First Aid				

Drugs	antiseptic, Lidocaine hydrochloride 2.5% - External analgesic. Sold under the following brands: a) Good Neighbor Pharmacy NDC 24385-593-46 , b) Quality Choice, NDC 63868-0488-02; c) Select Brand NDC 15127-885-59; d) Premier Value UPC 4098602556; e) Rite Aid Pharmacy UPC 011822576871; f) TopCare UPC 3680033436; g) Vida Mia UPC 847717060718; h) Humco 2 fl. oz NDC 0395-1637-92 i) Humco 3 fl. oz. NCD 0395-1637-93 ; 2 fl OZ (59 mL) and 3 FL OZ (90 mL) bottles, HUMCO, Texarkana, TX 75501.	a) Good Neighbor Pharmacy Mercuroclear 2 fl. oz, Lots: ALL LOTS b) Quality Choice Mercuroclear ... More	Class II	Microbial Contamination of Non-Sterile Product(s): The product was found to be contaminated with Bulkholderia sp.	Humco Holding Group, Inc
Devices	ZYM B Reagent (REF 70493) ZYM B reagent is an additional test used to reveal the results of some miniaturized biochemical test included in the API strips. The API product line is a standardized system combining several biochemical tests, which enables group or species identifications of microorganisms.	Lot numbers: 1002171010, 1002295110, 1002360360, 1002421440, 1002485410, 1001951820, 1002011320, and 1002071020.	Class II	bioMérieux identified a visual defect and activity issue on the ZYM B reagent (REF 70493); leading to a false negative results of some API biochemical tests using the ZYM B reagent.	Biomerieux France Chemin De L'Or
Devices	API Listeria (REF 10300) API Listeria is a standardized system for the identification of Listeria which uses miniaturized tests, as well as a database. The ZYM B reagent is including in API Listeria kit and it is used as an additional reagent for revealing the result of DIM miniaturized biochemical test included in the API Listeria strips. ZYM B reagent is added in the DIM test before reading miniaturized biochemical test including in the API Listeria strips.	Lot numbers: 1002210010, 1002210011, 1002287930, 1002287931, 1002350760, 1002390940, 1002390941, 1002518070, 1002518071, 1002518072, 1001915090, 1001915091, 1001915092, 1001932340, 1001998120 and 1002129350.	Class II	bioMérieux identified a visual defect and activity issue on the ZYM B reagent (REF 70493); leading to a false negative results of some API biochemical tests using the ZYM B reagent.	Biomerieux France Chemin De L'Or
Devices	API NH (REF 10400) API NH is a standardized system for the identification of Neisseria, Haemophilus (and related genera) and Moraxella catharrhalis (Branhamella catarrhalis), which uses miniaturized tests, as well as a specially adapted database. API NH also enables the biotyping of Haemophilus influenza and Haemophilus parainfluenxzae, as well as the detection of a penicllinase.	Lot numbers: 1001896203, 1001957530, 1001957531, 1002112170, 1002112171, 1002112172, 1002279351, 1002340500, 1002112173, 1002171111, 1002171110, 1002279350, 1002279352, 1002340501, 1002340502, 1002340503, 1002412550, 1002412551, 1002485910, 1002485911, 1002455912.	Class II	bioMérieux identified a visual defect and activity issue on the ZYM B reagent (REF 70493); leading to a false negative results of some API biochemical tests using the ZYM B reagent.	Biomerieux France Chemin De L'Or
Biologics	Platelets Pheresis Leukocytes Reduced	W039413489620 (2 units)	Class II	Blood products, for which the platelet yield was not sufficient to support the products being split into two parts, were distributed.	OneBlood, Inc.
Biologics	Red Blood Cells Frozen Leukocytes Reduced	W039713746412J	Class II	Blood product, which was incorrectly labeled as negative for the S red cell antigen, was distributed.	Aurora Area Blood Bank Dba Heartland Blood Centers
Biologics	Red Blood Cells (Apheresis) Leukocytes	038FS27049 (2 units)	Class II	Blood products, collected from a donor with a history of Hepatitis A exposure,	American Red Cross Blood Svs. Indiana-Ohio

	Reduced			were distributed.	Region
Biologics	Platelets Pheresis Leukocytes Reduced	W115113269757J	Class II	Blood product, with a low platelet count, was distributed.	LifeSouth Community Blood Centers, Inc.
Biologics	Red Blood Cells Leukocytes Reduced	W0423130201404	Class II	Blood products, which tested negative for West Nile Virus (WNV) using pooled testing, but were not tested for WNV by individual donor testing, were distributed.	Blood Systems, Inc
Biologics	Platelets Pheresis Leukocytes Reduced	W0423130201412	Class II	Blood products, which tested negative for West Nile Virus (WNV) using pooled testing, but were not tested for WNV by individual donor testing, were distributed.	Blood Systems, Inc
Biologics	Red Blood Cells (Apheresis) Leukocytes Reduced	W042313038777T	Class III	Blood product, which did not meet the minimum requirement for Red Blood Cell recovery following leukoreduction, was distributed.	Blood Systems, Inc
Biologics	Red Blood Cells Leukocytes Reduced	W041613034464M	Class III	Blood product, for which the quality control testing for the Hemoflow shaker was not documented, was distributed.	Blood Systems, Inc. DBA United Blood Services
Drugs	BuPROPion Hydrochloride Extended-Release Tablet (XL) 150mg, Rx only, a) 30 count bottle(NDC 0591-3331-30), b) 90 count bottle (NDC 0591-3331-19), c) 500 count bottle (NDC 0591-3331-05), Manufactactred By: Watson Laboratories, Inc. Corona, CA 92880	Lots: 524099M, 524100A, 521687A	Class III	Failed Dissolution Specifications: Failed stability testing for dissolution test at 18 months.	Actavis Inc
Drugs	Hydravax High Potency Diuretic Weight Loss Solution, Pharmaceutical Grade, 45 capsules per bottle, Dietary Supplement, Manufactured and Distributed by Metabolic Nutrition, Sunrise, Florida, www.metabolicnutrition.com	ALL LOTS	Class I	Marketed Without an Approved NDA/ANDA; this product is being recalled for containing an undeclared diuretic called Triamterene, an FDA approved prescription only medication used to treat edema, making it an unapproved new drug	IQ Formulations, LLC
Devices	Orthofix Firebird Spinal Fixation System Instrumentation Modular Screw Driver, Product Usage: The Modular Screw Driver is used for inserting a modular bone screw into the pedicle during a spinal fixation procedure. It is a reusable instrument.	Production Identification Numbers: Part Number 52-1332, All Lot Numbers.	Class II	Orthofix received 6 complaints which resulted in reportable events due to extended surgical times greater than 30 minutes for the Modular Screw Driver (PN 52-1332). The complaints alleged that the screw driver's collet would malfunction resulting in the surgeon being unable to use the Modular Screw Driver to effectively place Modular Screws, which may result in a delay of surgery.	Orthofix, Inc.
	GE Healthcare CARESCAPE Monitor B650 and CARESCAPE Monitor B850. The CARESCAPE Monitor B650 is a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility. The CARESCAPE Monitor B650 is intended for use on adult, pediatric, and				

Devices	neonatal patients and on one patient at a time. The CARESCAPE Monitor B650 is indicated for monitoring and recording of, and to generate alarms for, hemodynamic (including ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output, temperature and mixed venous oxygen saturation), impedance respiration, airway gases (CO2, O2, N2O and anesthetic agents), spirometry, gas exchange, and neurophysiological (including electroencephalography, Entropy, Bispectral Index (BIS) and neuromuscular transmission) status. The CARESCAPE Monitor B650 can be a stand-alone monitor or interfaced to other devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network. The CARESCAPE Monitor B650 is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility. The CARESCAPE Monitor B650 is not intended for use during MRI. The CARESCAPE Monitor B850 is a multi-parameter high acuity patient monitor intended for use in multiple areas within a professional healthcare facility. The CARESCAPE Monitor B850 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE Monitor B850 system is indicated for monitoring of Hemodynamic (including ECG, ST Segment, Arrhythmia Detection, ECG Diagnostic Analysis and Measurement, Invasive Pressure, Noninvasive Blood Pressure, Pulse Oximetry, Cardiac Output, Temperature, Impedance Respiration and SvO2 (Mixed Venous Oxygen Saturation), Airway Gases (Fi/Et C02, 02, N20 and Anesthetic Agent), Spirometry, Gas Exchange (02 Consumption (VO2), C02 production (VCO2), energy expenditure (BE), and respiratory quotient (RQ)) and neurophysiological (including electroencephalography (EEG), Entropy, Bispectral Index (BIS) and Neuromuscular Transmission (NMT)	Mfg Lot or Serial # System ID SED11107669GA 2020913-002 SED12102371GA 2020913-002 SED12455369GA 2020913-002 SED13027435GA 2020913-002 SED13027444GA 2020913-002 SEW11456764HA ... More	Class II	GE Healthcare has recently become aware of potential safety issues associated with the CARESCAPE Monitor B850 and CARESCAPE Monitor B650. These included 25 issues related to NIBP (Non-InvasiVentilation Alarms:ve Blood Pressure) , ECG, Central Monitor, General, Tram, and Bed to Bed Issues.	GE Healthcare, LLC

	Monitoring) status. The CARESCAPE Monitor B850 provides alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices. The CARESCAPE Monitor B850 can be a stand-alone monitor or interfaced to other devices. It can also be connected to other monitors for bed to bed viewing and to data management software devices via a network. The CARESCAPE Monitor B850 is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility. In addition to the healthcare practitioner, the CARESCAPE Monitor B850 is designed to provide configuration and troubleshooting capabilities to qualified service personnel. The CARESCAPE Monitor B850 is not intended for use during MRI.				
Biologics	The PLASMACELL-C disposable set in overpouch is a single unit open system consisting of the PLASMACELL-C separation device (containing the membrane filter), the reinfusion reservoir, two (2) transducer protectors, two (2) solution spikes, one (1) female Luer for plasma container connection and one (1) male Luer for needle connection.	Model: 4R2256; Lot Numbers and Expiration Dates: FA13J23098, expires 10/31/2015; FA13J24153 expires 10/31/2015; FA13K07107 expires 11/30/2015; and, FA13K07115 expires 11/30/2015.	Class II	PLASMACELL-C Disposable Set for Use with SPIKESMART System, with a defect in the base of the blue vent cap on the reservoir assembly that may result in a leak of the reservoir assembly, was distributed.	Fenwal Inc
Devices	Teflon Tube, sterile T2 Humerus System Stryker Trauma GmbH Prof Kuntscher Str 1-5 24232 Sconkidrchen, Germany distributed in the USA by: Stryker Howmedica Osteonics Corp.: Mahwah, NJ 07430 USA 510 K042396 Used in several T2 systems intended to support the exchange of the Ball Tip Guide Wires for Smooth Tip Guide Wires: T2 Tibial Nailing Systems, T2 Femoral Nailing Systems, T2 Ankle Nailing Systems, and T2 Humerus Nailing Systems	Catalog Number 1806-0073S Lot Code K06C3B4, K05ECF3, K05ECF2, K057298, K0432D3	Class II	Stryker became aware during laboratory testing that there is a potential that the seal integrity of the outer pouch (sterile barrier) may be compromised for certain lots of the product Teflon Tube, sterile.	Stryker Howmedica Osteonics Corp.
Devices	Carestream DRX Evolution System (Standard Q) The DRX-Evolution System (Standard Q) is a permanently installed diagnostic x-ray system for generation of x-rays for examination of various anatomical regions. These products are permanently installed diagnostic x-ray systems composed of 4 main components: an operator console, over head tube crane, x-ray tube assembly including a collimator and stationary	Serial Numbers 5049, 5073, 5133, 5162	Class II	Carestream received a report of an exposure being initiated without a patient image captured. The patient was imaged 2 times before an image was captured. The field engineer who visited the site reported the system allowed an exposure without the assignment of a bucky or image receptor.	Carestream Health Inc.

	generator. In addition the device can use an x-ray table and /or wallstandbucky to complete x-ray exposures.				
Biologics	Sterile Diluent for Allergenic Extracts, 10% Glycerin w/v, 9 mL vial packaged in 25-count vials per carton, Rx only, Greer Laboratories, Inc., Lenoir, NC 28645; Item SG2507192.	Lot #190874, Exp 11/16	Class III	Sterile Diluent for Allergenic Extracts, with lack of assurance of sterility, was distributed.	Greer Laboratories Inc
Veterinary	OroCAM is supplied in three glass vial sizes containing 6 mL, 11 mL and 33 mL of meloxicam. Each vial has a different metered dose pump delivering a dose of 0.25 mg, 0.50 mg, or 1.075 mg, per spray, respectively. Manufactured for Abbott Laboratories; North Chicago, IL 60064 USA; Product of Spain	*** US PRODUCTS *** 1) 6 mL Vials. List Number 04943-04-01. Lot Codes and ... More	Class II	Abbott Animal Health is voluntarily recalling the ten lots of OroCAM (meloxicam) Transmucosal Oral Spray for Dogs due to the possibility that some animals could receive an incorrect dose during administration. A limited number of units from lots FEBU-2 and FEBU-3 were found to contain incorrect pumps.	Abbott Laboratories
Devices	Compressor Mini To provide a supply of dry, filtered compressed air for a medical respiratory ventilator or anaesthesia machine that meet the specifications of the compressor mini. compressor mini is intended to be operated by healthcare providers, physicians, nurses, and technicians. Compressor mini is to be used only for bedside application within the hospital environment. Compressor mini is neither intended nor suitable for use during in-hospital patient transportation or during ambulance or air transportation. Compressor mini is not suitable for use with MRI.	Part number 6481779	Class II	Maquet Compressor Mini may deliver compressed air at a temperature higher than specified.	Maquet Cardiovascular Us Sales, Llc
Devices	The ACUTE Innovations Modular RibLoc System (RibLoc U plus) is comprised titanium plates and screws that are used to stabilize rib fractures, fusions and osteotomies during the normal bone healing process. The plates are manufactured from titanium and the screws are manufactured from titanium alloy. Surgical instrumentation is supplied with the implants in a surgical tray to facilitate the proper insertion of the plates and screws. The ACUTE Innovations Modular RibLoc System is intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs, and for reconstructions of the chest wall and sternum. Part Numbers: RBL1301- 50 mm Rib Plate; RBL1302- 75 mm Rib Plate; RBL1303- 115 mm Rib Plate; RBL1304- 155 mm Rib Plate; RBL1305- 215 mm Rib Plate;	LOT numbers: RBL1301 for 50 mm Rib Plate: L1209002; L1302002; L1308001; RBL1302 for 75 mm Rib Plate: L1209003; L1302003; RBL1303 for 115 mm Rib Plate: L1209004; L1302004; RBL1304 for 155 mm Rib Plate: L1209005; RBL1305 for 215 mm Rib Plate: L1209006;	Class II	The ACUTE Innovations Ribloc U plus Rib Fracture Plating System is recalled because it has the potential to malfunction during installation in a surgery.	ACUTE Innovations, LLC

Devices	Port Kit with Access Infusion Set under the following labels: 1) 8F/SL/Plastic Port/F, Product Number H965450140, Catalog Number 45-014; 2) 8F/SL/Titanium Ports/NF, Product Number H965450170, Catalog Number 45-017; 3) 6F/SL/Plastic Port/F, Product Number H965450200, Catalog Number 45-020; 4) 8F/SL/Plastic Port/F, Product Number H965450220, Catalog Number 45-022; 5) 8F/SL/Titanium Ports/F, Product Number H965450250, Catalog Number 45-025; 6) Plastic/6F/non-filled/non-valved, Product Number H965450290, Catalog Number 45-029; 7) Plastic/6F/filled/non-valved, Product Number H965450300, Catalog Number 45-030; 8) Plastic/8F/non-filled/non-valved, Product Number H965450310, Catalog Number 45-031; 9) Plastic/8F/filled/non-valved, Product Number H965450320, Catalog Number 45-032; 10) Plastic/6F/non-filled/valved, Product Number H965450370, Catalog Number 45-037; 11) Plastic/6F/filled/valved, Product Number H965450380, Catalog Number 45-038; 12) Plastic/8F/non-filled/valved, Product Number H965450390, Catalog Number 45-039; 13) Plastic/8F/filled/valved, Product Number H965450400, Catalog Number 45-040; 14) Titanium/6F/non-filled/valved, Product Number H965450410, Catalog Number 45-041; 15) Titanium/8F/non-filled/valved, Product Number H965450430, Catalog Number 45-043. Product Usage: ***K-Shield Port Access Infusion Set, (affected product) supplied by Kawasumi Laboratories. The K-Shield Port Access Infusion Set with High Pressure Tubing is an intravascular administration set with a non-coring Huber needle that is used to access an implanted medication port for solution infusion. This device is also indicated for injection of contrast media by a power injector only with power injectable implanted port.***NMI Port is indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics,	Batch/Lot Numbers: 4688881, 4688883, 4688884, 4688885, 4688887, 4668695, 4654060, 4654060, 4659108, 4668699, 4654061, 4659109, 4668700, 4654062, 4659110, 4668701, 4654063, 4658398, 4662581, 4664985, 4675021, 4681156, 4654064, 4654065, 4658399, 4658400, 4662583 and 4675023	Class II	Navilyst Medical has recalled a Port Kit with Access Infusion Set due to a possible breach of sterilization barrier.	Navilyst Medical, Inc.

	nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal.				
Devices	Standard tubing set, Synergetics, Inc., length 10 ft, sterile / EO, 17570. Packed 6 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M269420	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Chow Illuminated Pick, Synergetics, inc., length 7.5 ft, sterile / EO, 56.07.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M272660	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Stiff 25ga Chow Illuminated Pick (Dull), Synergetics, inc., length 8.0 ft, sterile / EO, 56.07.25PS. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M258430 and M265950	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Chandelier Infusion Cannula, Synergetics, inc., 20ga, length 7.5 ft, sterile / EO, 56.30.P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M261320	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Chandelier Infusion Cannula, Synergetics, inc., length 8.0 ft, sterile / EO, 56.30.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M260620, M265860, M267100, and M269230	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Awh Chandelier, Synergetics, inc., length 8.0 ft, sterile / EO, 56.50.25P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M269200	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	29ga Oshima Dual Chandelier, Synergetics, inc., length 7.5 ft, sterile / EO, 56.50.29P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M25990, M263810, M265710, and M271040	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Awh Chandelier, Synergetics, inc., B&L Cannula Compatible, length 8.0 ft, sterile / EO, 56.52.25P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M266040 and M269190	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Awh Vivid Chandelier, Synergetics, length 7.5 ft, sterile / EO, 56.54.25P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M261810	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	27ga ONE-STEP (tm) Awh/Tano Vivid Chandelier, Synergetics, length 8.0 ft, sterile / EO, 56.55.27P. Packed 12 units per box. Manufactured for	Lot number: M254140	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc

	Synergetics, Inc., O'Fallon, MO.				
Devices	23ga Straight Fixed Extended Illuminated Laser Probe, Synergetics, length 7.5 ft, sterile / EO, 55.62.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M259970 and M267870	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Endo Illuminator, Synergetics, inc., 20ga, length 7.0 ft, sterile / EO, 56.02. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M270130	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Endo Illuminator (Eckardt Trocar Compatible), Synergetics, inc., length 8.0 ft, sterile / EO, 56.02.23P Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M257130 and M265370	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Endo Illuminator, Synergetics, inc., length 7.0 ft, sterile / EO, 56.02.25 Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M260010 and M275520	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Stiff 25ga Endo Illuminator, Synergetics, inc., length 7.5 ft, sterile / EO, 56.02.25PS. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M271440	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	27ga ONE-STEP (tm) Endo Illuminator, Synergetics, inc., length 7.5 ft, sterile / EO, 56.02.27P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M262090	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	"The Corona" Shielded Wide Field Endo Illuminator, Synergetics, inc. 20ga, length 7.0 ft, sterile / EO, 56.12. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M266740	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Wide Field Corona Endo Illuminator, Synergetics, inc., length 7.5 ft, sterile / EO, 56.12.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M264050, M269440, and M277900	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Wide Field Corona Endo Illuminator, Synergetics, inc., length 7.5 ft, sterile / EO, 56.12.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M262080 and M270970	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
	Two-Port Vitrectomy (TPV (tm)) Wide Field High Flow End Irrigator, Synergetics, inc., 19ga, length 7.0 ft,	Lot numbers: M264400,		Faulty seals on the outer pouch of various, double-	

Devices	sterile / EO, 56.14. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	M265330, and M270010	Class II	pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Vivid (tm) Endo Illuminator, 20ga, Synergetics, inc., length 7.5 ft, sterile / EO, 56.20P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M274760	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Wide Field Endo Illuminator, Vivid (tm) Endo Illuminator, 20ga, Synergetics, inc., 20ga, length 7.5 ft, sterile / EO, 56.21P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M264060	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Wide Field Endo Illuminator, Synergetics, inc., length 7.5 ft, sterile / EO, 56.21.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M261310, M262650, M263630, M265960, and M268970	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	Stiff 25ga Wide Field Endo Illuminator, Synergetics, inc. length 7.5 ft, sterile / EO, 56.21.25PS. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M260800, M262050, M263140, M264420, and M267440	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Mid-Field Endo Illuminator, Synergetics length 7.5 ft, sterile / EO, 56.22.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M270550	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Mid-Field Endo Illuminator, Synergetics, length 7.5 ft, sterile / EO, 56.22.25P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M276380	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	23ga Aspirating Endo Illuminator, Synergetics, length 7.5 ft, sterile / EO, 56.24.23P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot numbers: M265310 and M262070	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
Devices	25ga Aspirating Endo Illuminator, Synergetics, length 7.5 ft, sterile / EO, 56.24.25P. Packed 12 units per box. Manufactured for Synergetics, Inc., O'Fallon, MO.	Lot number: M271960	Class II	Faulty seals on the outer pouch of various, double-pouched, single-use, sterile, ophthalmic devices could result in seal failure.	Synergetics Inc
	Symmetry and CODMAN (R) brands, QUAD-LOCK (TM) Sterilization Container. Sterilization container systems manufactured and distributed under the following names: Small Symmetry and CODMAN (R) brands, QUAD-LOCK (TM) Sterilization Container Small Perforated Bottom, REF 50-8731, 270mm x 270mm x 100mm, QTY: 1,				

Devices	Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Perforated Bottom, REF 50-8732, 270mm x 270mm x 135mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Perforated Bottom, REF 50-8733, 270mm x 270mm x 150mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Perforated Bottom, REF 50-8734, 270mm x 270mm x 200mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Perforated Bottom, REF 50-8735, 270mm x 270mm x 260mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Non-Perforated Bottom, REF 50-8744, 270mm x 270mm x 100mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Non-Perforated Bottom, REF 50-8745, 270mm x 270mm x 135mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Non-Perforated Bottom, REF 50-8746, 270mm x 270mm x 150mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Non-Perforated Bottom, REF 50-8747, 270mm x 270mm x 200mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Small Non-Perforated Bottom, REF 50-8748, 270mm x 270mm x 260mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Lid Grey Small 4 Latch, REF 50-8950, 280mm x 276mm, QTY: 1,	all lots	Class II	The Quad-Lock(TM) Sterilization Container System may not maintain an effective sterile barrier.	Symmetry Medical/SSI

	Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Lid Yellow Small 4 Latch, REF 50-8951, 280mm x 276mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Lid Green Small 4 Latch, REF 50-8952, 280mm x 276mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Lid Blue Small 4 Latch, REF 50-8953, 280mm x 276mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Lid Red Small 4 Latch, REF 50-8954, 280mm x 276mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Lid Black Small 4 Latch, REF 50-8955, 280mm x 276mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Medium Symmetry and CODMAN (R) brands, QUAD-LOCK (TM) Sterilization Container Medium Perforated Bottom, REF 50-8736, 440mm x 270mm x 100mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Medium Perforated Bottom, REF 50-8737, 440mm x 270mm x 135mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive, Antioch, TN 37013 Symmetry and CODMAN(R) brands, QUAD-LOCK (TM) Sterilization Container Medium Perforated Bottom, REF 50-8738, 440mm x 270mm x 150mm, QTY: 1, Symmetry Surgical, Inc., 3034 Owen Drive,				
Devices	AnspacSingle use Sterile bone cutting burs.h REF: S-1504TD Twist Drill for 1.5mm x 4mm screw. Rx only Single use Sterile bone cutting burs.	Lot #'s: D293037349, D323038110 and D363039140	Class II	Cutter was longer than was stated on the label.	The Anspach Effort, Inc.
Devices	Anspach REF: TURQ-434-4 Twist Drill for 1.5mm x 4mm screw. Rx only Single use Sterile bone cutting burs.	Lot #'s: D323038131 and D343038845	Class II	Cutter was longer than was stated on the label.	The Anspach Effort, Inc.
Food	Hnos. Perez brand cactus leaves (pads): distributed by: West Coast Produce	Product number 58164	Class III	State of California, Department of Pesticide Regulation samples Cactus Pads and found the following pesticides that are not permitted in the	West Coast

	300 Franklin St. Oakland, CA 94607			US: Permethrin - 0.094 ppm; Chlorpyriphos - 0.136 ppm; Monocrotophos - 0.030 ppm.	Produce, LLC
Food	Mexpogroup Cactus Grown in Mexico; 44 lbs, 20 KG; Calle El Rosario #20581 Col Buenos Aires Norte C.P. 22700 Tijuana, Mexico.	Lot 305083	Class II	CA Dept of Pesticide Regulation, Enforcement Branch, sampled Mexpogroup Cactus and found the following chemical which do not have a tolerance level in the US: Monocrotophos - 2.37 ppm; Carbendazim as Thiophanate Methyl - 0.154 ppm; Chlorothalonil - 3.61 ppm.	Shasta Produce
Devices	KODAK DirectView DR 7500 Dual Detector System, MODEL DR 7500, Manufactured by Carestream Health, Inc. 150 Verona Street Rochester, NY 14608. Made in U.S.A.	Service Code: 8087; Catalog numbers: 8791345, 1155118, 1295088, 8551046, 8791345, 1666700, 8531675	Class II	Carestream Health, Inc. has recalled DR 7500 Dual Detector System utilizing Version 5.X Software due to a possible patient image display error.	Carestream Health, Inc.
Devices	S5/C5 Heart-lung machine Product Usage: The StOckert S5/ Sorin C5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.	S5 Item Number: 10-80-00, 10-85-00, 28-9S-80, 28-95-8S. C5 Item Number: S8-00-00	Class II	Sorin is initiating a field correction on S5/C5 Heart-lung machine and CP5 centrifugal pump system due to reports of pump speed control knob failures resulting in no response.	Sorin Group Deutschland GmbH
Devices	CP5 centrifugal pump system Product Usage: The Stockert S5/ Sorin C5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.	Item Number: 60-02-60	Class II	Sorin is initiating a field correction on S5/C5 Heart-lung machine and CP5 centrifugal pump system due to reports of pump speed control knob failures resulting in no response.	Sorin Group Deutschland GmbH
Devices	SET SCREW RETAINING DRIVER, REF 3010000820, QTY: 1 EA, Medtronic Sofamor Danek, USA, Inc., 1800 Pyramid Place, Memphis, TN 38132. Screwdriver - orthopedic manual surgical instrument.	TI13J01811	Class II	The retaining tabs component of the Set Screw Retaining Drive may be oversized, which will not allow proper mating between the Set Screw Retaining Drive and the set screw.	Medtronic Sofamor Danek USA Inc
Food	Uncle Ben's (R), Infused(R) Rice Mexican Flavor rice, NET WT 5 LB (2.27 kg), distributed by MARS Foodservices US, P.O. Box 5059, Rancho Dominguez, CA 90224-5059	332DMGRV01	Class II	The firm received reports of flushing reactions after consumption of product led to concern of possible production issue.	Mars Food US
Food	Condies Food fine shred lettuce, and 1/4 shred lettuce; 5 lbs bags, 4 bags per case	Fine shred lettuce 1-7; 1/4 shred lettuce 1-6	Class II	A piece of hard brittle plastic was found inside a bag of 41890 Lettuce Shred Fine. The bag of lettuce had the following code date: Use Thru 1/7. Upon receipt of a picture of the plastic, it was determined that the plastic had originated from an instrument used by Condies Foods for quality control purposes. It is believed that there is a possibility that additional pieces may be within other bags of product. As a precaution, Condies Foods has decided to recall any product which potentially may have been affected.	Condies Foods, Inc
	Radial Assist RAD BOARD, used to support the weight of a patient's arm and supplies for a medical			Merit Medical Systems, Inc. is voluntarily recalling one lot (B507171) of RAD BOARD RB 100 devices.	

Devices	procedure. The Merit RAD BOARD is a rigid and stiff body board intended for use for various medical purposes. RAD BOARD was specifically designed to support the weight of a patient's arm and supplies for medical procedure, in order to have optimal access to upper extremity vasculature, including radial and brachial arterial and venous access. The RAD BOARD is partially lined with a layer of lead-free Xenolite TB for additional radiation scatter protection.	lot B507171	Class II	The affected devices are missing the main label which graphically depicts patient orientation on the board. The issue may allow the board to be oriented in the wrong direction where the semi-radiopaque material in the board (embedded Xenolite) could obscure patient anatomy during fluoroscopy. There have been no reports of patient harm or injury from Merit customers as a result of this issue. Merit has chosen to remove this lot from the field by replacing the unlabeled RAD BOARDs.	Merit Medical Systems, Inc.
Devices	Tapered Screw-Vent Implant, MTX, 4.7mm x 11.5mm, 4.5mm Platform. Catalog Number TSVWB11, Lot 62470008. Class II, 510 (k) K13227.	Catalog Number TSVWB11, Lot 62470008.	Class II	Zimmer Dental is conducting a voluntary recall of a single lot of the Tapered Screw-Vent Implant, Catalog TSVWB11, Lot 62470008, because some of the packages of this lot may have the Cap Label state Ø3.7 x 10mm instead of Ø4.7 x 11.5mm.	Zimmer Dental Inc
Food	Walmart Great Value Tex Mex Trail Mix, Net Wt 28 oz (793g), Distributed by Wal Mart Stores, Inc., Bentonville, AR, packed in rigid clear plastic jars.	Best By date range: 04/18/2014 through 12/12/2014, UPC: 0 78742 03371 6	Class II	Product contains undeclared allergen; milk.	Ann's House of Nuts, Inc
Devices	ACUSON SC2000 Ultrasound System; Power Input: 100-240VAC, 1600W Max, 50/60 Hz. Manufacturer: Siemens Medical Solutions USA, Inc. 685 East Middlefield Road Mountain View, CA 94043 SC2000 ultrasound imaging system is intended for Cardiac, neo-natal and fetal cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal interoperative, Intraoperative Neurological, Musculo-skeletal Conventional and musculo-skeletal Superficial Applications. The system also provided the ability to measure anatomical structures and calculation packages that provide information to the clinician that my be used adjunctively and with other medical data obtained by a physician for clinical diagnosis purposes.	Model number 10433816; Serial numbers lower than 401100. Serial numbers: 400935 400686 400597 400833 400140 400753 400752 400771 401016 400166 400635 400582 400983 400532 400580 400592 400804 400733 400737 400652 401036 400643 400746 400349 400784 400919 400685 400777 400186 400499 400896 400809 400259 400282 400758 400762 400831 400723 400402 400633 ... More	Class II	The user interface assembly on the ACUSON SC2000 may become loose with the potential for the entire module to fall off of the ultrasound system.	Siemens Medical Solutions USA, Inc.
Devices	Simplexa" Flu A/B & RSV Direct assay, Model MOL2650. The Focus Diagnostics Simplexa Flu A/B & RSV Direct assay is intended for use on the 3M Integrated Cycler instrument for the in vitro qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs (NPS) from human patients with signs and symptoms of respiratory tract infection in conjunction	Model Number MOL2650 Lot Numbers: 24493, 24495, 24535, 24536.	Class II	Focus Diagnostics is initiating an urgent safety notice correction for Simplexa Flu A/B & RSV Direct assay (MOL2650) because Focus Diagnostics has received some customer complaints of Simplexa Flu A/B & RSV lots due to sporadic false	Focus Diagnostics Inc

	with clinical and epidemiological risk factors. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans and is not intended to detect influenza C.			positive RSV signals, which may result in a higher RSV false positive rate.	
Devices	ACUSON SC2000 Power Input: 100-240VAC, 1600 Max 50/60Hz; Siemens Medical Solutions USA, Inc. 685 East Middlefield Road Mountain View, CA 94043 Ultrasound imaging system.	Model 10433816; Serial numbers: 401283 401284 401377 401291 401275 401208 401316 401337 401376 401390 401159 401188 401191 401223 401400 401143 401325 401371 401368 401232 401140 401393 401239 401128 401196 401133 401334 401273 401225 401210 401144 401229 401209 401288 401142 401120 401121 401123 401189 401260 401338 401344 401329 401253 401295 401217 401192 401119 401312 401389 401126 401224 401227 401276 401293 401214 401317 401199 401240 401219 401238 401242 401218 401362 401349 401395 401382 401173 401122 401215 401179 401270 401313 401203 401340 401264 401357 401167 401222 401310 401206 401352 401164 401263 401201 401354 401299 401162 401298 401205 401339 401171 401296 401262 401353 401318 401289 401186 401254 401183 401195 401374 401398 401145 401157 401331 401399 401381 401356 401146 401153 401200 401220 401129 401178 401151 401152 401259 401147 401211 401228 401230 401233 401301 401231 401148 401321 401277 401332 401113 401150 401272 401274 401292 401302 401303 401304 401131 401367 401394 401154 401161 401306 401118 401185 401127 401180 401197 401379 401271 401286 401307 401216 401279 401280 401322 401323 401327 401115 401134 401111 401267 401268 401269 401287 401117 401282 401155 401181 401182 401226 401156 401257 401351 401397 401348 401290 401387 401244 401258 401314 401247 401194 401187 401365 401149 401300 401326 401333 401335 401336 401116 401236 401347 401204 401141 401311 401366 401370 401137 401245 401175 401285 401237 401369 401392 401234 401256 401383 401250 401360 401346 401241 401345 401246 401315 401193 401320 401294 401177 401114 401135 401136 401138 401255 401110 401176 401169 401174 401363	Class II	The locking mechanism that is intended to hold the control panel in a fixed position can become loose and fail to lock the rotation of the control panel, making it unable to steer or control during transport.	Siemens Medical Solutions USA, Inc.

		401278 401386 401328 401385 401132 401243 401124 401373 401378 401391 401361 401343 401375 401108 401109 401384 401235 401252 401198 401213 401158 401319 401184 401308 401265 401266 401305 401130 401248 401249.			
Food	Simply balanced, herb mixed freeze dried vegetables all natural, Ingredients: Super sweet corn, edamame, peas, carrots, (carrots, sugar, dextrose, tapioca starch), Italian seasoning (Garlic, tomato (tomato, salt), crushed red pepper, basil, oregano), coconut oil, sea salt. May contain peanut, tree nuts, milk, soy, and wheat., Net WT 2.5 oz (71 g), UPC 0 85239 08318 5, distributed by Target Corporation, Minneapolis, MN 55403.	Lot #: 205X317, 213X317, 253X317. Best By: 24JUL14; 01AUG14; 10SEPT14	Class II	Amport Foods is recalling a limited amount of Target Simply Balanced Herb Mixed Freeze Dried Vegetable due to a potential for undeclared soy.	American Importing Co, Inc
Devices	ARIATELE TELEMETRY TRANSMITTER, Model 96281, with SpO2 Option C. Model 96281 is intended for use with either adult or neonatal patient populations in a hospital environment.	Serial Numbers IN the US: 6281- 002002, 6281- 002003, 6281- 002004, 6281- 002005, 6281- 002006, 6281- 002007, 6281- 002008, 6281- 002009, 6281- 002010, 6281- 002011, 6281- 002012, 6281- 002013, 6281-000295, 6281-000401, 6281-000402, 6281-000403, 6281-000404, 6281-000405, 6281-000406, 6281-000407, 6281-000408, 6281-000503, 6281-000504, 6281-000505, 6281-000506, 6281-000507, 6281-000508, 6281-000512, 6281-000513, 6281-000514, 6281-000515, 6281-000516, 6281-000517, ... More	Class II	The AriaTele Model 96281 with SpO2 monitoring Option C is recalled because the AriaTele (transmitter) display and the Telemetry Central Station display may show a SpO2 value when the sensor is not connected to the patient or in certain sensor failed conditions.	Spacelabs Healthcare, Llc
Devices	BD BACTEC FX- Top Unit instrument, catalog number 441385, and Bottom Unit instrument, catalog 441386, available as a single or a stack configuration; Manufactured by BD Diagnostic Systems, 7 Loveton Circle, Sparks, MD 21152. The BD BACTEC FX instrument is designed for the rapid detection of bacteria and fungi in clinical specimens. Samples are drawn from patients and injected directly into BACTEC culture vials, which are placed into the instrument for incubation and testing.	Catalog number 441385 and 441386	Class II	Improperly functioning component of a diagnostic medical device may cause false negative results in clinical specimens.	Becton Dickinson & Co.
Devices	BD BACTEC FX 40 instrument, catalog number 442296, manufactured by BD Diagnostic Systems, 7 Loveton Circle, Sparks, MD 21152. The instrument is designed for the rapid detection of bacteria and fungi in clinical specimens. Samples are drawn from patients and injected	Catalog number 442296	Class II	Improperly functioning component of a diagnostic medical device may cause false negative results in clinical specimens.	Becton Dickinson & Co.

	directly into BACTEC culture vials, which are placed into the instrument for incubation and testing.				
Food	Marlyce's Homemade Butterballs	no specific code provided; recall applies to all product in commerce	Class I	Undeclared allergens. The product label does not declare allergens of Wheat Flour, Soy Flour, Whey, and Milk.	L. M. Noodle Company, LLC
Devices	Accuray CyberKnife Robotic Radiosurgery System; Accuray Incorporated Sunnyvale, CA. Indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy.	Part number: 054000-001; Serial numbers in US: C0022 C0030 C0037 C0042 C0045 C0046 C0047 C0048 C0049 C0051 C0052 C0053 C0055 C0056 C0057 C0058 C0059 C0061 C0062 C0063 C0064 C0067 C0068 C0070 C0071 C0072 C0074 C0078 C0079 C0080 C0088 C0090 C0091 C0092 C0094 C0095 C0097 C0098 C0099 C0100 C0101 C0102 C0103 C0106 C0108 C0109 C0111 C0112 C0114 C0118 C0119 C0122 C0123 C0126 C0127 C0128 C0131 C0132 C0133 C0134 C0135 C0136 C0137 C0139 C0141 C0143 C0144 C0146 C0149 C0150 C0151 C0152 C0155 C0158 C0159 C0160 C0162 C0163 C0165 C0174 C0177 C0178 C0179 C0181 C0182 C0183 C0184 C0186 C0192 C0194 C0196 C0197 C0198 C0199 C0200 C0201 C0203 C0205 C0206 C0207 C0208 C0209 C0210 C0213 C0214 C0219 C0220 C0222 C0223 C0224 C0225 C0226 C0233 C0243 C0244 C0246 C0247 C0248 C0252 C0253 C0254 C0256 C0257 C0259 C0260 C0261 C0262 C0263 C0273 C0274 C0278 C0283 C0284 C0285 C0290 C0291 C0293 C0296 C0303 C0304 C0312 C0316 C0323 C0332 C0335 C0336 C0338 C0343 C0124 Out of US: C0202 C0231 C0238 C0351 C0170 C0171 C0235 C0267 C0282 TBD C0032 C0054 C0060 C0093 C0105 C0110 C0113 C0115 C0117 C0125 C0130 C0154 C0161 C0175 C0176 C0180 C0185 C0187 C0188 C0189 C0191 C0195 C0204 C0211 C0215 C0216 C0217 C0218 C0221 C0227 C0228 C0230 C0232 C0234 C0236 C0237 C0240 C0242 C0245 C0249 C0251 C0255 C0264 C0265 C0266 C0268 C0269 C0270 C0272 C0275 C0276 C0277 C0279 C0286 C0287 C0288 C0292 C0294 C0295 C0299 C0305 C0306 C0309 C0314 C0315 C0319 C0321 C0322 C0324	Class II	Potential Safety issue with Synchrony Boom Arm Mounting Assembly - one complaint of mounting assembly detaching.	Accuray Incorporated

		C0325 C0326 C0330 C0334 C0337 C0339 C0342 C0344 C0348 C0349 C0006 C0007 C0008 C0012 C0013 C0014 C0019 C0020 C0033 C0190 C0193 C0241 C0281 C0300 C0307 C0308 C0313 C0320 C0327 C0329 C0331 C0333 C0340 C0341 C0347 C0038 C0041 C0065 C0073 C0075 C0076 C0077 C0084 C0085 C0086 C0087 C0089 C0107 C0120 C0121 C0138 C0140 C0145 C0147 C0148 C0157 C0166 C0168 C0169 C0173 C0212 C0229 C0239 C0258 C0271 C0280 C0289 C0297 C0298 C0301 C0302 C0310 C0317 C0345.			
Food	Fresh Cactus ("Nopal"), 40lbs/bx	Lot Code: 1209-12	Class II	Marquez Produce is recalling Fresh Cactus because of unapproved pesticides.	Marquez Produce Inc.
Food	Cactus Leaves/pads ("Nopales"), 40 lbs	Lot Number: 1228-12	Class II	Marquez Produce is recalling cactus leaves due to unapproved pesticides.	Marquez Produce Inc.
Food	Cactus Pads (Nopal) Mexpogroup: Product of Mexico	44 lb crate - lot 14-5126	Class III	Unapproved pesticides were found by the CA Department of Pesticide Regulation during sampling,	Washington Vegetable Co
Devices	Atlantis PV, 8.5F, 15 MHz Peripheral Imaging Catheter: Sterile, R; Sterilized using irradiation. Product Usage: This catheter is a 15 MHz ultrasound imaging catheter intended to operate with an IVUS instrument for diagnostic imaging. It is used with an 8.5F-introducer sheath and a 0.035 guidewire.	Product number: H749364560, Catalog number: 36456; Lot numbers: 16159358, 16183964, 16230195, 16230673, 16247263, 16257809, 16268498, 16289177, 16311356, 16330543, 16342824, 16419885, 16420624, 16420903, 16447744, 16458536, 16486133, 16494530; Expiration Date: June 11th 2014 to October 29th 2014.	Class II	Reports of physicians experiencing inability to pass a 0.035" guidewire through the guidewire lumen and exit port at the (proximal) Y-manifold of the imaging catheter.	Boston Scientific Corporation
Food	Monarch Breakfast Syrup, in 1.5 oz. portion control cups, Distributed by US Foods, Inc., Rosemont, IL 60018.	Lot #14006M, UPC #758108012714	Class I	Undeclared allergen; peanuts	Sauer Company The C F
Devices	Brilliance iCT & Brilliance iCT SP Computed Tomography X-Ray Systems, Philips Healthcare, Cleveland, OH The Brilliance iCT and iCT SP are whole body Computed Tomography X-Ray Systems intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.	Brilliance iCT: 728306, Serial #'s: 100018, 100040, 100411, 100503, 100506 Brilliance iCT SP: 728311, Serial #'s: 200047, 200121	Class II	Patient images exhibited ring artifacts.	Philips Medical Systems (Cleveland) Inc
	InnerCool RTx Endovascular System, Model Numbers: 861470 (120V), 861472 (240V). Product Usage: The InnerCool RTx device is a			Phillips Healthcare initiated this action because the Main Control Board (MCB)	

Devices	thermal regulating system intended to induce, maintain and reverse mild hypothermia, to achieve and/or maintain normothermia, and for use in fever reduction. K080908	Model Numbers: 861470 (120V), 861472 (240V).	Class II	may produce an inaccurate low patient temperature reading and low temperature alarm.	Philips Healthcare
Food	NatureBox Picante Ranch Mix Spicy Snack Mix with Corn Nuts and Masa Chips; Net. WT: 4 oz. (113 g), Stand up Pouch, Vegan Ingredients: Corn Nuts (corn, canola oil, soybean oil, salt), Sugar, Flax Chips (Yellow corn masa, flax seeds, soybean oil, salt) Snack Seasoning(sour cream, salt, whey, corn syrup, tomato, maltodextrin, garlic powder, onion powder, cheddar cheese ([pasteurized milk, cheese cultures, salt, enzymes], whey, buttermilk solids, salt, disodium phosphate), milk, vinegar, soybean oil, citric acid, spice, parsley), corn Syrup, chili Powder, Red Pepper. No UPC on product. Distributed by NatureBox, San Carlos, CA 94070	all lot codes with expiration date of 4/1/14 (includes consumer facing lot codes 3BC13324, 4BC13339, 5BC13340, 5BC13354, 5BC14003, 4BC13009). Supplier lot code 13274.	Class II	It was discovered that the specification used by the supplier was incorrect and therefore the ingredient statement was incorrect and did not include unbleached wheat flour and bulgur wheat. The packaging does note that the products are packaged in a facility that also processes tree nuts, peanuts, milk, wheat, egg and soy.	NatureBox, Inc.
Food	NatureBox Salsa Spiced Nut Mix; Net. WT: 4 oz. (113 g), Stand up Pouch, Vegan Ingredients: Almonds, Corn chips with flax (yellow corn masa, flax seed, soybean oil, salt), Cashews, seasoning (tomato powder, salt, sugar, onion powder, garlic powder, spices, cilantro, lime juice powder, corn syrup, lime juice, lime oil, paprika, soybean oil), corn syrup, sugar. No UPC on product. Distributed by NatureBox, San Carlos, CA 94070	Expiry dates of 3/16/14, 4/21/14 and 6/19/14. (includes consumer facing lot codes 2BC13323, 2BC13330, 1BC13294. Supplier lot codes 13259, 13323 and 13360. 4BC13339, 3BC13552, 1BC14006, 5BC14010, 1BC14013)	Class II	It was discovered that the specification used by the supplier was incorrect and therefore the ingredient statement was incorrect and did not include unbleached wheat flour and bulgur wheat. The packaging does note that the products are packaged in a facility that also processes tree nuts, peanuts, milk, wheat, egg and soy.	NatureBox, Inc.
Devices	GE Healthcare Innova IGS 630. Biplane Cardiovascular and Interventional Imaging System. Product Usage: The angiographic X-ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures. The Cathiab Frontiers solutions are indicated for use in conjunction with single plane and biplane GE angiographic X-ray systems and imaging / data medical devices used	Serial # System ID 00000616724BU1 956389IGS630 00000618156BU4 MCMIGS630 FMI12200DUMMY2 702731ANGIO2 00000619372BU6 732828IGS30 00000618158BU0 210705CATH1 00000622076BU9 661327IGS630 00000621314BU4 904202WCL2 00000628656BU1 281MHWCL1 00000622220BU2 303839CL4 00000625357BU9 281420LAB3BP 00000626085BU5 817BGIGS630 00000628654BU6	Class II	GE Healthcare has recently become aware of a potential safety issue with respect to IGS 630 Imaging Systems. While performing fluoroscopy on a biplane fluoroscopy unit, there is a potential for loss of the x-ray imaging function when the user changes the size of the	GE Healthcare, LLC

	in interventional and surgical cathlab environments and cleared for commercial distribution. The Cathiab Frontiers solutions are integrated GE angiographic X-ray and imaging / data medical devices that simplify the end-to-end clinical workflow in the cathlab by implementing: 1) Communication protocols for exchanging and automatically synchronizing patient, exam, system, and image information between the angiographic X-ray systems and the imaging / data medical devices. 2) Communication protocols for the control of imaging / data medical device functions from the angiographic X-ray systems user interface. 3) Interfaces for displaying the imaging / data medical device output on the monitor display solutions of the GE angiographic X-ray systems.	215576IGS4 FMI12200DUMMY3 CS1340VA01 00000614683BU1 M4152252 00000618160BU6 YV1900 00000617143BU3 YV1901 00000618157BU2 YV1902 00000620495BU2 YV1903 00000624842BU1 YV1904 00000627935BU0 YV1905 00000630300BU2 YV1906 00000617142BU5 YV1950 FMI12200DUMMY4 YV1907 00000622672BU4 850060746 00000626239BU8 850060749 FMI12200DUMMY1 SA2308VA01 00000622221BU0 ZA2239VA01 00000614682BU3 34006VAS02		lateral FOV (Field of View) and releases the biplane footswitch pedal simultaneously. This could lead to a system lock up requiring a restart of the system in order to recover its operations. No injury has been reported due to this issue.	

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