

**RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II**

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**PRODUCT**

Smokey Q Barbecue Sauce, Good-N-Thick 128 fl. oz., (one gallon); Ingredient: Corn Syrup, Water, Tomato Paste, Vinegar, Salt, Modified Food Starch, Natural Smoke Flavor, Soybean Oil, spice Extracts, Onion Powder, Garlic Powder, Red 40, Blue 1. Recall # F-2232-2010

**CODE**

Lot 51210, Exp 5/12/11

**RECALLING FIRM/MANUFACTURER**

Vineland Syrup Inc., Vineland, NJ, by telephone on May 19, 2010 and by letters on May 20, 2010 and by visit. Firm initiated recall is ongoing.

**REASON**

Smokey Q Barbecue Sauce made by Vineland Syrup Inc., contains soy sauce that contains wheat, not currently listed on the ingredient list.

**VOLUME OF PRODUCT IN COMMERCE**

900 gallons

**DISTRIBUTION**

NJ, PA

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**PRODUCT**

Pet 100% Orange Juice Beverage, packaged in 4 ounce paper cartons, 75 cartons/case. Recall # F-2233-2010

**CODE**

Sell by dates: 05/15/10, 05/17/2010, 05/21/2010, 05/23/10, 05/29/10

**RECALLING FIRM/MANUFACTURER**

Land-of-Sun LLC, Richmond, VA, by letter on May 10, 2010. Firm initiated recall is ongoing.

**REASON**

Manufacturer distributed a beverage ingredient, which does not declare Yellow #5 on the label.

**VOLUME OF PRODUCT IN COMMERCE**

252,121 cartons

**DISTRIBUTION**

TN, WV, VA, NC, SC, GA

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**PRODUCT**

Marshmallow Crispy Treats Now with Chocolate Rainbow Sparkles, 12 count per retail package, Net Wt 14.04 oz. Recall # F-2234-1020

**CODE**

Lot #'s: 100971, 100981, 101041, 101051, 101091, 101121, 101131, 101171, 101181, 101251, 101321 and 101331

**RECALLING FIRM/MANUFACTURER**

Jtm Foods, Inc., Erie, PA, by telephone on May 21, 2010. Firm initiated recall is ongoing.

**REASON**

The product contains undeclared colors – FD&C Yellow #5 and FD&C Yellow #6.

**VOLUME OF PRODUCT IN COMMERCE**

4,000 cases (12 retail packages /case)

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Mayfield Orange Drink, Naturally and Artificially Flavored, Half Pint (236 mL). Recall # F-2235-2010

**CODE**

DMS #28566, Lot numbers: 4/08/10, 4/12/10, 4/13/10, 4/17/10, 4/22/10, 4/26/10, 4/29/10 and 5/03/10

**RECALLING FIRM/MANUFACTURER**

Mayfield Dairy Farms, LLC, Braselton, GA, by letter on/about May 10, 2010. Firm initiated recall is ongoing.

**REASON**

Product contains undeclared FD&C color Yellow #5.

**VOLUME OF PRODUCT IN COMMERCE**

475,500 units

**DISTRIBUTION**

GA

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**PRODUCT**

Atomic Orange, Naturally Orange Flavored Juice Beverage with other Natural flavors, 8 fl. oz. (236 mL). Recall # F-2236-2010

**CODE**

Sell by dates: 04-04-2010, 04-15-2010, 04-19-2010, 04-29-2010, 05-05-2010

**RECALLING FIRM/MANUFACTURER**

Land-of-Sun Dairies, LLC, Baxley, GA, by letter on/about May 10, 2010. Firm initiated recall is ongoing.

**REASON**

Product contains undeclared FD&C color Yellow #5.

**VOLUME OF PRODUCT IN COMMERCE**

231,679 units

**DISTRIBUTION**

GA, SC

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**PRODUCT**

\*\*\*PLANTILLAS PARA TACOS\*\*\*Mantengase Refrigerado/\*\*\*Keep Frozen or Refrigerated\*\*\*Plantillas\*\*\*Del\*\*\*Pepino\*\*\*Products come in three different sizes: 15 units, 18 units, 50 units. Recall # F-2237-2010

**CODE**

Lot # 42810 and Lot # 42910

**RECALLING FIRM/MANUFACTURER**

Plantillas Del Pepino, Inc., San Sebastian, PR, by letter April 28, 2010. Firm initiated recall is ongoing.

**REASON**

Product contains undeclared FD&C colors – Yellow #5, Yellow #6, and Red #40.

**VOLUME OF PRODUCT IN COMMERCE**

834 packages

**DISTRIBUTION**

PR

**RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II**

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**PRODUCT**

1) Haloperidol Decanoate IM Injection, 50 mg/ml, Vials, Rx only, NDC 0703-7011-03 (Pkg. 10 vials). Recall # D-592-2010;

2) Haloperidol Decanoate IM Injection, 50 mg/ml, Vials, Rx only, NDC 0703-7013-01 (Single vials). Recall # D-593-2010

**CODE**

1) Lot # 07N113, Exp 10/2010; Lot # 31300760B, Exp 2/2011; Lot # 31303087B, Exp 7/2011; Lot # 31305311B, Exp 1/2012; Lot # 31307740B, Exp 6/2012; Lot # 31307741B, Exp 6/2012; Lot # 31309924B, Exp 11/2012; Lot # 31310249B, Exp 12/2012;

2) Lot # 07H108, Exp 6/2010; Lot # 08A126, Exp 1/2011; Lot # 31303429B, Exp 8/2011; Lot # 31304893B, Exp 11/2011; Lot # 31306358B, Exp 3/2012; Lot # 31308616B, Exp 9/2012; Lot # 31309837B, Exp 11/2012

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Teva Pharmaceuticals USA, Inc., Sellersville, PA, by letters on April 22, 2010.

Manufacturer: Teva Parenteral Medicines Inc., Irvine, CA. Firm initiated recall is ongoing.

**REASON**

Impurities/Degradation Products: Product does not meet impurity specifications.

**VOLUME OF PRODUCT IN COMMERCE**

335,616 vials

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Ultram ER (tramadol HCl) Extended-Release Tablets, 100 mg, a) 30 count bottle, NDC 0062-0653-30, b) Physician samples 4 count blister pack, NDC 0062-0653-01, Rx only. Recall # D-594-2010

**CODE**

a) Lot #s P08H006, Exp June 2010; P08I008, Exp June 2010; P08I009, Exp June 2010; P08J012, Exp July 2010; P08J014, Exp July 2010; P08K017, Exp August 2010; P08K019, Exp August 2010; P09B017, Exp August 2010; P09B018, Exp August 2010; 09A006P, Exp November 2010; 09A007P, Exp November 2010; 09A008P, Exp November 2010; 09A013P, Exp November 2010; 09A014P, Exp November 2010; b) Lot numbers: 9AA3276, Exp September 2010; 9AA3276P1, Exp September 2010

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Ortho-McNeil Pharmaceutical, Inc., Raritan, NJ, by letters on May 27, 2010.

Manufacturer: Biovail Corp., Steinbach Manitoba, Canada. Firm initiated recall is ongoing.

**REASON**

Does Not Meet Sustained Release Specifications: Certain lot numbers may release the active ingredient at a slightly faster rate than required by the products release specification at the 8 hour and 10 hour time points.

**VOLUME OF PRODUCT IN COMMERCE**

245,941 bottles; 368,760 physician samples

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Ketotifen Ophthalmic Solution Eye Drops, 5 mL (0.17 FL OZ) Bottle, Sterile, OTC. The product was distributed under the following labels: (1) equate brand: Eye Itch Relief Drops, NDC 49035-299-12; (2) Target brand: eye drops itch relief, NDC 11673-299-12; (3) Walgreens brand: Eye Itch Relief; NDC 0363-299-12; (4) Premier Value brand: Eye Itch RELIEF DROPS, NDC 59726-299-12; (5) DISCOUNT drug mart brand: EYE ITCH Relief Drops, NDC 59726-299-12; (6) Kroger brand: EYE ITCH Relief Drops, NDC 30142-299-12; (7) AMERICAN FARE brand: EYE ITCH RELIEF DROPS, NDC 59726-299-12; (8) GOOD NEIGHBOR PHARMACY brand, NDC 24385-0494-64; (9) Equaline brand: eye itch relief, NDC 59726-299-12; (10) RITE-AID brand: Antihistamine Eye Drops; (11) GOODSENSE brand: Allergy Itchy Eye Relief Drops, NDC 59726-012-17; (12) TopCare brand: Eye Itch, NDC 59726-299-12; (13) CAREONE brand: EYE ITCH Relief Drops, Made in Canada; (14) H-E-B brand: Eye Itch RELIEF DROPS, NDC 59726-299-12; (15) CVS brand: EYE ITCH RELIEF, NDC 59726-299-12. Recall # D-595-2010

**CODE**

Lot numbers: T0533 (Exp. date 5/28/2010); T0534 (Exp. date 5/28/2010); T0647 (Exp. date 6/28/2010); T0648 (Exp. date 6/28/2010); T0836 (Exp. date 7/28/2010); T0837 (Exp. date 8/28/2010); T0864 (Exp. date 7/28/2010); T0865 (Exp. date 7/28/2010); T0944 (Exp. date 8/28/2010); T1084 (Exp. date 10/28/2010); U0855 (Exp. date 5/28/2011); U0856 (Exp. date 5/28/2011); U1099 (Exp. date 6/28/2011), U1100 (Exp. 7/28/2011), U1388 (Exp. 8/28/2011)

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: PI Developments, Inc., Westbury, NY, by letter dated March 29, 2010 and April 9, 2010. Firm initiated recall is ongoing.

**REASON**

Failed PH Specifications: out of specification (OOS) results for pH during stability testing.

**VOLUME OF PRODUCT IN COMMERCE**

1,412,398 Bottles

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Red Yeast Rice 0.4%, powder in 25kg cardboard drum. Recall # D-597-2010

**CODE**

All production lots and codes sold during the period of 1/2008 to 1/2010

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Pacific Rainbow International Inc., City of Industry, CA, by letter on January 14, 2010.

Manufacturer: Hangzhou Boda Biological Tech Co., Ltd., Hangzhou, China. Firm initiated recall is ongoing.

**REASON**

Product contains an unapproved new drug, marketed without an NDA/ANDA (contains higher than naturally occurring amounts of Lovastatin).

**VOLUME OF PRODUCT IN COMMERCE**

5700 Kg

**DISTRIBUTION**

Nationwide

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**PRODUCT**

1) AMOXICILLIN for Oral Suspension USP 250 mg per 5 mL in 80 ml bottles. Rx only, NDC 0093-4155-79. Recall # D-599-2010;

2) AMOXICILLIN for Oral Suspension USP 250 mg per 5 mL in 100 ml bottles. Rx only, NDC 0093-4155-73. Recall # D-600-2010;

3) AMOXICILLIN for Oral Suspension USP 250 mg per 5 mL in 150 ml bottles. Rx only, NDC 0093-4155-80. Recall # Recall # D-601-2010

**CODE**

1) Lot number 35410395A;

2) Lot numbers 35400826A, 35405154A, 35405163A, 35405389A, 35405394A, 35405403A, 35406134A, 35407009A, and 35414041A;

3) Lot numbers: 35405034A, 35406014A, 35407134A, 35408993A, 35414055A, exp 5/2012, and 35414062A exp 6/2012

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Teva Pharmaceuticals USA, Inc., Sellersville, PA, by letters on March 4, 2010, March 22, 2010, and April 20, 2010.

Manufacturer: Novopharm Ltd., Scarborough Ontario, Canada. Firm initiated recall is ongoing.

**REASON**

Superpotent (Single Ingredient Drug): Samples had 116.7g and 118.8g which resulted in an excess dosage 218% of label claim and 222% of label claim.

**VOLUME OF PRODUCT IN COMMERCE**

410,477 bottles

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Nifediac CC (Nifedipine) Extended Release Tablets, 60 mg 100 count bottle, Rx only, NDC 0093-1022-01. Recall # D-603-2010

**CODE**

Lot #'s: 0804T28 exp 4/2010 and 0807T25 exp 5/2010

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Biovail Pharmaceuticals, Mississauga, Canada, by letter on April 13, 2010.

Manufacturer: Biovail Corp., Steinbach Manitoba, Canada. Firm initiated recall is ongoing.

**REASON**

Dose Not Meet Sustained Release Specifications: Active ingredient may release slightly faster than required by product release rate specification.

**VOLUME OF PRODUCT IN COMMERCE**

18,923 bottles

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Compressed Medical Oxygen USP in A, C, D and E steel cylinders, Rx only. Each cylinder is identified with four labels which read in part: 1) "OXYGEN, COMPRESSED U.S.P. UN 1072" For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, RX only. 2) "Property Of SOS Sound Oxygen Service Please call for pick up if equipment needs service". 3) The third label is an individual bar code that is a unique identifier for each cylinder "SOS C Tank C1283". 4) The fourth label is a small grocery-type sticker with the lot number and expiration date of that cylinder "1011012110 LOT #". Recall # D-604-2010

**CODE**

Cylinder Expiration Dates: Lots 112100541 through 114100547 Exp. 02/23/2015; Lots 114100561 through 114100563 Exp. 02/25/2015; Lots 101100611 through 101100615 Exp. 03/02/2015; Lots 103100641 through 105100649, 1051006410 and 1051006412 Exp. 03/05/2015; Lots 106100681 through 108100689, 108100691, 108100692, 1081006810 and 1081006811 Exp. 03/09/2015; Lots 114101111 through 114101116 Exp. 04/21/2015. Cylinder item # (Unique Bar Code identifying each individual cylinder): C0071, C0325, E1774, E1904, A0010, A00D5, A0241, E0430, E2087, C0126, C0256, C0606, C0683, C1130, C1287, E1055, E0070, E0078, E1721, E1856, D0082, E1265, E4542, C0179, C0574, C0733, C1056, C1324, E0345, D0049, E0560, E0554, E1418, E1789, E1933, E2121, E0387, E0639, E1054, E1305, E1791, E1820, E2107, E1073, E1170, E1509, E0082, E0311, E1243, E1939, E1962, E2064, E0234, E1023, E1511, E2293, E2296, E1902, C0095, C0343, C0359, C0569, C0737, C0738, C0993, C1063, C1108, C1196, D0035, A0049, C0829, C1127, C0565, C0758, C1092, C0149, C0307, C1041, C1088, C1157, E0160, E0286, C0051, C0180, C0769, C1187, EZ126, C0637, C0871, D0737, C0177, C0187, C0735, E0028, E0284, E0288, E0691, E0710, E0721, E1147, E1199, E1347, E1838, E1862, E1944, E2069, E2150, E2240, E2268, E2347, E2348, E2350, E2351, E2353, E2357, E2311, E2314, E2317, E2319, E2322, E2323, E2332, A0147, C0054, C1076, C1270, D0034, E0607, E1227, E1591, E1322, C0067, C0956, E1709, E2081, E0033, E0457, E1935, E2049, E2153, E1837, E1922, E2051, E0762, C0174, C1102, C1150, D0821, E0156, E0296, A0288, C0225, C0518, C0524, C0696, C0703, C0865, C1126, C1171, D0024, D0027, D0046, D0066, D0105, D0165, D0206, D0280, D0283, D0316, D0419, D0513, D0527, D0538, D0689, D0700, D0743, D0802, D0812, C0001, C0201, C0301, C0765, C0819, C0959, C0972, C1006, C1199, C1303, E0047, E0131, E0330, E0334, E0453, E0605, E1157, E1385, E1595, E1931, E2055, E2230, E2282, D0050, D0166, D0191, D0516, D0704, D0755, D0830, E0025, E0136, E0550, E0635, E0682, E1067, E1132, E1223, E1334, E1461, E1598, E1771, E2039, E2052, E2054, E2167, E2289, E2308, E2355, E0042, E0100, E0159, E0454, E0532, E0536, E0549, E0557, E1037, E1117, E1187, E1259, E1319, E1364, E1706, E1756, E1768, E1869, E1873, E2115, E2127, E2142, E2295, E2337, E2354, E0018, E0278, E0358, E0531, E0558, E0749, E1008, E1120, E1272, E1285, E1341, E1400, E1596, E1757, E1795, E1831, E1878, E1950, E1968, E2053, E2091, E2130, E2140, E2148, E2213, E2241, E2258, E2271, E2288, E0379, E0609, E0615, E0723,

E0739, E0759, E0761, E1072, E1241, E1281, E1513, E1593, E1916, E1923, E1928, E1998, E2183, E2265, E2326, E0378, D0088, E0083, E1177, E1256, E2079, E2232, E2236, E1751, and E2229. The firm also uses a manufacturing (filling) lot code: 101100611, 101100612, 101100613, 101100614, 101100615, 103100641, 103100642, 103100643, 104100644, 104100645, 104100646, 104100647, 105100648, 105100649, 106100681, 106100682, 106100683, 106100684, 106100685, 107100686, 107100687, 107100688, 107100689, 108100691, 108100692, 112100541, 112100542, 112100543, 113100544, 114100545, 114100546, 114100547, 114100561, 114100562, 114100563, 114101111, 114101112, 114101113, 114101114, 114101115, 114101116, 1051006410, 1051006412, 1081006810 and 108100681

**RECALLING FIRM/MANUFACTURER**

Sound Oxygen Service, Inc., Auburn, WA, by visit beginning April 29, 2010. Firm initiated recall is ongoing.

**REASON**

CGMP Deviations: Lack of documentation that prefill, fill and/or post-fill testing of cylinders and finished products was performed.

**VOLUME OF PRODUCT IN COMMERCE**

310 cylinders (Size A: 3; Size C: 68; Size D: 33; Size E: 206)

**DISTRIBUTION**

WA

**RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III**

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**PRODUCT**

Paroxetine Tablets, USP, 40 mg, 30-count bottles, Rx only; NDC 65862-157-30. Recall # D-559-2010

**CODE**

Lot # PEP410005-A, Exp 12/11

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Aurobindo Pharma USA, Dayton, NJ, by letters on April 16, 2010.

Manufacturer: Aurobindo Pharma Limited, Hyderabad, Andhra Pradesh, India. Firm initiated recall is ongoing.

**REASON**

Labeling: Label Mix-Up: some bottles labeled as Paroxetine 40 mg tablets actually contain Citalopram 20 mg tablets.

**VOLUME OF PRODUCT IN COMMERCE**

20,424 bottles

**DISTRIBUTION**

Nationwide

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**PRODUCT**

1) Triamcinolone Acetonide Injectable Suspension, USP, 50 mg/5 mL (10 mg/mL), Rx only, 1 x 5 mL Multidose Vial, NDC 0781-3243-75. Recall # D-590-2010;

2) Triamcinolone Acetonide Injectable Suspension, USP, 40 mg/mL, Rx only, 1 x 1 mL Vial, NDC 0781-3245-72. Recall # D-591-2010

**CODE**

- 1) Lot number: 150937;
- 2) Lot numbers: 153856, 154043

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Sandoz Incorporated, Broomfield, CO, by letter on June 9, 2010.  
Manufacturer: Sandoz Canada Inc., Boucherville, Canada. Firm initiated recall is ongoing.

**REASON**

Failed USP Content Uniformity Requirements: Drug was out of specification for redispersibility at the 12 month time point.

**VOLUME OF PRODUCT IN COMMERCE**

179,445 units

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Tretinoin Cream, 0.025% Tretinoin topical cream, 20 gram tubes Rx only, NDC 4580218202.  
Recall # D-598-2010

**CODE**

Lot & Exp 9AM459 JAN 2011 , 9DM626 April 2011, and 9EM634 May 2011

**RECALLING FIRM/MANUFACTURER** Recalling Firm: L. Perrigo Co., Allegan, MI, letter on March 10, 2010.

Manufacturer: Ortho Pharmaceutical Division of Janssen Ortho LLC, Manati, PR. Firm initiated recall is ongoing.

**REASON**

Labeling: Label Error on Declared Strength: Tretinoin Cream 0.025% was packaged in tubes labeled as Tretinoin Cream 0.1%.

**VOLUME OF PRODUCT IN COMMERCE**

82,866 tubes

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Sulfacetamide Sodium Topical Suspension USP, 10% (Lotion), 118mL (4 fl oz) Bottle, Rx only; NDC 51672-1346-8. Recall # D-602-2010

**CODE**

Lots: G9101 expiration date July 2011, H9026 expiration date August 2011

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Taro Pharmaceuticals USA, Inc., Hawthorne, NY, by letters dated March 30, 2010.  
Manufacturer: Taro Pharmaceuticals, Inc., Brampton Ontario, Canada. Firm initiated recall is ongoing.

**REASON**

Labeling: Label w/Wrong or Incorrect EXP. Date: The product is mislabeled with an incorrect (extended) expiration period of 24 months.

**VOLUME OF PRODUCT IN COMMERCE**

3,638 units

**DISTRIBUTION**

Nationwide



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**PRODUCT**

1) Clear Nicotine (nicotine) Transdermal System Patch, 7 mg delivered over 24 hours, 14 Patches Per Box, OTC: 1) Equate; 2) Rugby, NDC 0536-5894-88; 3) Meijer, NDC 41250-894-88. Recall # D-606-2010;

2) Clear Nicotine (nicotine) Transdermal System Patch, 14 mg delivered over 24 hours, 14 Patches Per Box, OTC: 1) Equate; 2) Rugby, NDC 0536-5894-88; 3) Equaline; 4) Premier Value/CDC, NDC 68016-895-88; 5) Meijer, NDC 41250-895-88. Recall # D-607-2010;

3) Clear Nicotine (nicotine) Transdermal System Patch, 21 mg delivered over 24 hours, 14 Patches Per Box, OTC; 1) equate; 2) Rugby brand: Clear Nicotine Transdermal System, NDC 0536-5896-88; 3) Equaline; 4) Premier Value/CDC, NDC 68016-896-88; 5) Meijer, NDC 41250-896-88; 6) Duane Reade. Recall # D-608-2010

**CODE**

1) Units: 37263, 38038, 38221, 38443, 38475, 38695;

2) Units: 37263, 38038, 38221, 38443, 38475, 38695;

3) Units: 37030, 37166, 37261, 37548, 37561, 37648, 37653, 37705, 37714, 37731, 37815, 37848, 37849, 37850, 37906, 37922, 37923, 37988, 37989, 37990, 37991, 38061, 38062, 38063, 38112, 38113, 38263, 38259, 38260, 38261, 38269, 38341, 38376, 38471, 38472, 38473, 38604, 38536, 38474, 38633, 38691, 38694, 38722, 38776, 38605, 38606, 38693, 38632, 38634, 38866, 38867

**RECALLING FIRM/MANUFACTURER**

AVEVA Drug Delivery Systems, Inc., Miramar, FL, by letter and telephone on January 18, 2010 and February 2, 2010. Firm initiated recall is ongoing.

**REASON**

Aveva Drug Delivery Systems, Inc., FL is recalling multiple lots of Nicotine Transdermal System that could be subpotent or have myosmine and beta-nicotyrine impurities above the 0.50% specification limit.

**VOLUME OF PRODUCT IN COMMERCE**

27,817,441 Boxes

**DISTRIBUTION**

NY, MI, Canada

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**PRODUCT**

Lorazepam Tablets, USP, 0.5 mg, 100 Tablets Bottle, Rx only, NDC 0781-1403-01. Recall # D-609-2010

**CODE**

Lot Number: 177265

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Sandoz, Inc., Princeton, NJ, by letter dated April 27, 2010.

Manufacturer: Sandoz Inc., Broomfield, CO. Firm initiated recall is ongoing.

**REASON**

Impurities/Degradation Products: The product exceeds the Related Compound C degradant specification prior to expiry.

**VOLUME OF PRODUCT IN COMMERCE**

39,650 bottles

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Quixin (levofloxacin) 0.5%, Sterile Topical Ophthalmic solution, 5 mL, Bottle-Dropper, Rx Only, NDC 68669-135-05. Recall # D-610-2010

**CODE**

Lot No. 114163, Expiration date: 5/2010; Lot No. 116626, Expiration date: 11/2010

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Santen Inc., Napa, CA, by letter on April 13, 2010.

Manufacturer: Santen Oy, Tampere, Finland. Firm initiated recall is ongoing.

**REASON**

Impurities/Degradation Products: out of specification levofloxacin-N-oxide (NOXO), a degradant of levofloxacin, stability test results was 0.59% at the 36 months stability (Specification limit is 0.5%).

**VOLUME OF PRODUCT IN COMMERCE**

84,410 bottles

**DISTRIBUTION**

Nationwide

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**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II****PRODUCT**

Source Plasma. Recall # B-1443-10

**CODE**

Units: 05ANCB2927, 05ANCB2106, 05ANCB1986

**RECALLING FIRM/MANUFACTURER**

Plasma Biological Services, Asheville, NC, by facsimile on December 15, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who was at risk for variant Creutzfeldt-Jakob Disease (vCJD), were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

CA

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**PRODUCT**

Source Plasma. Recall # B-1444-10

**CODE**

Units: 4020414265, 4020412231, 4020411195, 4020384136, 4020382910

**RECALLING FIRM/MANUFACTURER**

CSL Plasma Inc., Akron, OH, by electronic notification on December 12, 2008 and December 15, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who did not receive a complete physical examination, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

5 units

**DISTRIBUTION**

Germany, IL

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1446-10

**CODE**

Unit: W227709330718

**RECALLING FIRM/MANUFACTURER**

Mid-South Regional Blood Center, Memphis, TN, by facsimile on October 27, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who traveled to an area considered endemic for malaria, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

TN

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**PRODUCT**

1) Red Blood Cells Leukocytes Reduced. Recall # B-1447-10;

2) Red Blood Cells. Recall # B-1448-10

**CODE**

1) Unit: W227709012670;

2) Unit: W227709010498

**RECALLING FIRM/MANUFACTURER**

Mid-South Regional Blood Center, Memphis, TN, by facsimile on November 17, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who traveled to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

TN

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**PRODUCT**

1) Red Blood Cells. Recall # B-1451-10;

2) Fresh Frozen Plasma. Recall # B-1452-10

**CODE**

1) Units: W227709392471, W227709390798, W227708313034;

2) Units: W227709390798, W227708313034

**RECALLING FIRM/MANUFACTURER**

Mid-South Regional Blood Center, Memphis, TN, by facsimile on October 27, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor with a history of high risk behavior, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

5 units

**DISTRIBUTION**

TN

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**PRODUCT**

Source Plasma. Recall # B-1453-10

**CODE**

Units: 4590054884, 4590054380, 4590053950, 4590053385, 4590053089, 4590052523, 4590051779, 4590051556, 4590050586, 4590048999

**RECALLING FIRM/MANUFACTURER**

Octapharma Plasma, Inc., Jacksonville, FL, by e-mail on December 23, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who did not receive a complete physical examination, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

10 units

**DISTRIBUTION**

Austria

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**PRODUCT**

1) Red Blood Cells Leukocytes Reduced. Recall # B-1454-10;

2) Platelets Pooled Leukocytes Reduced. Recall # B-1455-10

**CODE**

1) Unit: W227009009931;

2) Pool # W227009007413 (includes unit W227009009931)

**RECALLING FIRM/MANUFACTURER**

Community Blood Center of Carolinas, Charlotte, NC, by telephone and facsimile on January 8, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who traveled to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

SC, NC

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**PRODUCT**

1) Platelets Pheresis Leukocytes Reduced Irradiated. Recall # B-1456-10;

2) Platelets Pheresis Leukocytes Reduced. Recall # B-1457-10

**CODE**

- 1) Unit: W044409403841;
- 2) Unit: W044409403841 (2 units)

**RECALLING FIRM/MANUFACTURER**

Northern Illinois Blood Bank dba Rock River Valley BC, Rockford, IL, by telephone on December 18, 2009. Firm initiated recall is complete.

**REASON**

Blood products, which were labeled as leukoreduced, but exceeded the acceptable limit for white blood cell count, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

TN, IL

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**PRODUCT**

Cryoprecipitated AHF, Pooled. Recall # B-1458-10

**CODE**

Units: W037909161775, W037909161947, W037909161959, W037909161958, W037909177533

**RECALLING FIRM/MANUFACTURER**

Blood Center of Iowa, Des Moines, IA, by telephone on February 2, 2010. Firm initiated recall is complete.

**REASON**

Blood products, which were labeled with extended expiration dates, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

5 units

**DISTRIBUTION**

WI, IA

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**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1460-10;
- 2) Platelets Pooled Leukocytes Reduced. Recall # B-1461-10

**CODE**

- 1) Unit: 6680001;
- 2) Pool # 5805493

**RECALLING FIRM/MANUFACTURER**

Florida's Blood Centers, Inc., Orlando, FL, by letter dated February 10, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who traveled to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

FL

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**PRODUCT**

Fresh Frozen Plasma (Apheresis). Recall # B-1462-10

**CODE**

Unit: W044608494684

**RECALLING FIRM/MANUFACTURER**

Gulf Coast Regional Blood Center, Houston, TX, by facsimile on October 13, 2008. Firm initiated recall is complete.

**REASON**

Blood product, which did not meet quality control specifications, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

TX

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1483-10

**CODE**

Unit: 53KL69878

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by telephone on December 18, 2008, email on December 19, 2008 and by fax on December 21, 2008. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1485-10

**CODE**

Unit: W149509304234

**RECALLING FIRM/MANUFACTURER**

Northern California Community Blood Bank, Eureka, CA, by telephone and fax on November 23, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Source Plasma. Recall # B-1487-10

**CODE**

Units: 6240193930, 6240182085

**RECALLING FIRM/MANUFACTURER**

CSL Plasma Inc., Tucson, AZ, by letter on October 28, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor whose scheduled physical exam was incomplete, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

IL

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1489-10

**CODE**

Unit: 53KG12737

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by email and fax on April 03, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

DC

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**PRODUCT**

Source Plasma. Recall # B-1491-10

**CODE**

Units: 4010338388, 4010337282, 4010323305, 4010321445, 40103132200, 4010311225, 4010309891, 4010305662, 4010303357, 4010300885, 4010368956, 4010362639, 4010360286, 4010359544

**RECALLING FIRM/MANUFACTURER**

ZLB Plasma, Cleveland, OH, by letter on October 28, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor whose scheduled physical exam was incomplete, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

14 units

**DISTRIBUTION**

IL

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**PRODUCT**

Plasma Frozen within 24 hours (FP24). Recall # B-1492-10

**CODE**

Unit: 041FL14369

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: American Red Cross Blood Services, Birmingham, AL, by fax on September 09, 2009.

Manufacturer: American Red Cross Blood Services Alabama Region, Huntsville, AL. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose scheduled physical exam was incomplete, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1494-10

**CODE**

Unit: 53FN41556

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by fax and email on April 14, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

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**PRODUCT**

Human Cornea Tissue. Recall # B-1498-10

**CODE**

Units: FM130908OS, FM130908OD

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Illinois Eye-Bank, Watson Gailey, Ann Arbor, MI, by letter dated February 23, 2010.

Manufacturer: Illinois Eye Bank, Watson Gailey, Bloomington, IL. Firm initiated recall is complete.

**REASON**

Human Corneas, recovered from an ineligible donor, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 corneas

**DISTRIBUTION**

IL, MI

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**PRODUCT**



- 1) Red Blood Cells. Recall # B-1515-10;
- 2) Cryoprecipitated AHF, Pooled. Recall # B-1516-10;
- 3) Fresh Frozen Plasma. Recall # B-1517-10

**CODE**

- 1) Units: 8542183, 4225132;
- 2) Unit: 4225132;
- 3) Unit: 8542183

**RECALLING FIRM/MANUFACTURER**

Community Blood Center, Dayton, OH, by letter dated April 2, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor taking the medication Proscar, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

4 units

**DISTRIBUTION**

OH

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**PRODUCT**

- 1) Red Blood Cells. Recall # B-1522-10;
- 2) Fresh Frozen Plasma. Recall # Recall # B-1523-10

**CODE**

- 1) and 2) Unit: 2431142

**RECALLING FIRM/MANUFACTURER**

Community Blood Center, Dayton, OH, by letter dated September 9, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who was taking the medication finasteride, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

OH

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**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1524-10;
- 2) Platelets. Recall # B-1525-10;
- 3) Recovered Plasma. Recall # B-1526-10

**CODE**

- 1), 2), and 3) Unit: 2374673

**RECALLING FIRM/MANUFACTURER**

Central Kentucky Blood Center Inc., Lexington, KY, by letter dated November 4, 2008 or by facsimile on November 5, 2008. Firm initiated recall is complete.

**REASON**

Blood products, which were not quarantined after receiving information concerning donor suitability, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

KY, Austria

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**PRODUCT**

Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-1527-10

**CODE**

Unit: W067109067876

**RECALLING FIRM/MANUFACTURER**

The Blood Center, New Orleans, LA, by telephone on February 26, 2010 and by electronic notification on February 28, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

LA

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1530-10

**CODE**

Unit: 24KS98469

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, River Valley Region, Louisville, KY, by electronic notification on February 17, 2010 and by letters dated February 17, 2010 and February 19, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

IN

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**PRODUCT**

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1531-10

**CODE**

Unit: W051509101095 (2 units)

**RECALLING FIRM/MANUFACTURER**

Memorial Blood Centers, Saint Paul, MN, by letters dated January 22, 2010 and February 25, 2010. Firm initiated recall is complete.

**REASON**

Blood products, with a low hemoglobin level, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

WI

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1532-10

**CODE**

Unit: W038109025323

**RECALLING FIRM/MANUFACTURER**

Florida's Blood Centers, Inc., Melbourne, FL, by letter dated February 3, 2010. Firm initiated recall is complete.

**REASON**

Blood product, which was not tested for HIV/HCV NAT, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

FL

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1533-10

**CODE**

Unit: W036909219876 (2 units)

**RECALLING FIRM/MANUFACTURER**

Blood Bank of Delmarva, Inc., Newark, DE, by letter dated March 16, 2010 and by facsimile on March 23, 2010. Firm Initiated recall is complete.

**REASON**

Blood products, collected from a donor who traveled to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

NJ

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1534-10

**CODE**

Unit: W053509075286 (2 units)

**RECALLING FIRM/MANUFACTURER**

Central Jersey Blood Center, Shrewsbury, NJ, by telephone on December 2, 2009 and by facsimile on December 9, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who traveled to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

NJ

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**PRODUCT**

Plasma Frozen within 24 hours (FP24). Recall # B-1535-10

**CODE**

Unit: 9526249

**RECALLING FIRM/MANUFACTURER**

Florida's Blood Centers, Inc., Leesburg, FL, by telephone on December 16, 2009 and by letter dated December 16, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who was at risk for variant Creutzfeldt-Jakob Disease (vCJD), was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

FL

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1536-10

**CODE**

Unit: 024KR46612

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, River Valley Region, Louisville, KY, by facsimile and electronic notification on December 21, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

KY

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1538-10

**CODE**

Unit: W042208002560D

**RECALLING FIRM/MANUFACTURER**

Blood Systems, Inc., Las Vegas, NV, by e-mail on February 12, 2010 and by letter dated March 17, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

LA

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**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1540-10;
- 2) Plasma Frozen within 24 hours (FP24). Recall # B-1541-10

**CODE**

1) and 2) Unit: 55V56567

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Greater Ozark-Arkansas Region, Little Rock, AR, by telephone and facsimile on February 17, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor for whom donor suitability was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

MO, AR

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1542-10

**CODE**

Unit: 72N429870

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers Inc - Birmingham Region, Birmingham, AL, by facsimile on April 3, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

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**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1544-10;
- 2) Plasma Frozen within 24 hours (FP24). Recall # B-1545-10

**CODE**

1) and 2) Unit: 19GE43943

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services Tennessee Valley Region, Nashville, TN, by telephone on February 11, 2010 and by letter dated February 11, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor for whom donor suitability was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

TN

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1547-10

**CODE**

Unit: 53FJ09097

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by facsimile and electronic notification on February 1, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

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**PRODUCT**

Source Plasma. Recall # B-1549-10

**CODE**

Units: AB1186561, AB1187071

**RECALLING FIRM/MANUFACTURER**

Bio-Save Resources Of Albuquerque LLC, Albuquerque, NM, by facsimile on February 18, 2010 and by e-mail on April 2, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who received a tattoo within 12 months of donation, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

UK

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1550-10

**CODE**

Units: W288609005745 (2 units)

**RECALLING FIRM/MANUFACTURER**

LifeSource, Glenview, IL, by facsimile on February 12, 2010. Firm initiated recall is complete.

**REASON**

Blood products, which were labeled as leukoreduced, but were not tested to verify white blood cell count, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

IL

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1561-10

**CODE**

Units: 032KP55224 Part A; 032KP55224 Part B

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross, Madison, WI, by facsimile on July 18, 2006. Firm initiated recall is complete.

**REASON**

Blood products, which did not meet the acceptable product specifications for release, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

MI

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1563-10

**CODE**

Unit: 17KW97332

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross - North Central Region, Saint Paul, MN, by facsimile on September 1, 2006. Firm initiated recall is complete.

**REASON**

Blood product, which was collected from a donor who traveled to a malaria endemic area, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MA

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1564-10

**CODE**

Units: 17GZ58716, 17KM70536

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross - North Central Region, Saint Paul, MN, by telephone on August 21, 2006 and by facsimile on August 24, 2006. Firm initiated recall is complete.

**REASON**

Blood products, which tested positive for red cell antibodies, but were missing antibody identification labels, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

MN, WI

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**PRODUCT**

1) Red Blood Cells Leukocytes Reduced. Recall # B-1565-10

2) Platelets Leukocytes Reduced. Recall # B-1566-10

**CODE**

1) and 2)) Unit: 17KZ75310

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross - North Central Region, Saint Paul, MN, by facsimile on September 6, 2006. Firm initiated recall is complete.

**REASON**

Blood products, which were collected from a donor who traveled to a malarial endemic area, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

MN, MA

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1567-10

**CODE**

Units: 17FL83961, 17GK25208

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross - North Central Region, Saint Paul, MN, by facsimile on September 19, 2006. Firm initiated recall is complete.

**REASON**

Blood products, which were collected from a donor who traveled to a malarial endemic area, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

NJ, MA

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1569-10

**CODE**

Units: 032KZ03636 Part A ;032KZ03636 Part B

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross, Madison, WI, by telephone on October 12, 2006. Firm initiated recall is complete.

**REASON**

Blood products, for which the quality control testing was incomplete, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

WI

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1570-10

**CODE**

Unit: 032GP41916



**RECALLING FIRM/MANUFACTURER**

The American National Red Cross, Madison, WI, by telephone on October 2, 2006. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

WI

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**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1584-10

**CODE**

Unit: 53G07729

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake and Potomac Region, Baltimore, MD, by telephone on February 16, 2010 and by letter dated February 16, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who traveled to an area considered endemic for malaria, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III**

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**PRODUCT**

Source Plasma. Recall # B-1445-10

**CODE**

Units: 3260000142, 3260000173, 3260004707, 3260005722

**RECALLING FIRM/MANUFACTURER**

Talecris Plasma Resources Inc., Lake Charles, LA, by facsimile on January 8, 2009. Firm initiated recall is complete.

**REASON**

Blood products, which reached unacceptable temperatures during storage, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

4 units

**DISTRIBUTION**

NC

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**PRODUCT**

1) Liquid Plasma, Recall # B-1449-10;

2) Platelets: Recall # B-1450-10

**CODE**

1) and 2) Unit: W227709392471

**RECALLING FIRM/MANUFACTURER**

Mid-South Regional Blood Center, Memphis, TN, by facsimile on October 27, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor with a history of high risk behavior, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

TN

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**PRODUCT**

Recovered Plasma. Recall # B-1484-10

**CODE**

Unit: 53KL69878

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by telephone on December 18, 2008, email on December 19, 2008 and by fax on December 21, 2008. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Recovered Plasma. Recall # B-1488-10

**CODE**

Unit: 53KG12737

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by email and fax on April 03, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Source Plasma. Recall # B-1490-10

**CODE**

Units: 4010407937, 4010407906, 4010407944, 4010407922

**RECALLING FIRM/MANUFACTURER**

ZLB Plasma, Cleveland, OH, by letter on August 14, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor whose suitability to donate was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

4 units

**DISTRIBUTION**

IL

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**PRODUCT**

Recovered Plasma. Recall # B-1495-10

**CODE**

Unit: 53FN41556

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by fax and email on April 14, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Recovered Plasma. Recall # B-1528-10

**CODE**

Unit: W067109067876

**RECALLING FIRM/MANUFACTURER**

The Blood Center, New Orleans, LA, by telephone on February 26, 2010 and by electronic notification on February 28, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

Switzerland

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**PRODUCT**

Recovered Plasma. Recall # B-1529-10

**CODE**

Unit: 24KS98469

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, River Valley Region, Louisville, KY, by electronic notification on February 17, 2010 and by letters dated February 17, 2010 and February 19, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Recovered Plasma. Recall # B-1537-10

**CODE**

Unit: 024KR46612

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, River Valley Region, Louisville, KY, by facsimile and electronic notification on December 21, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Recovered Plasma. Recall # B-1539-10

**CODE**

Unit: W042208002560D

**RECALLING FIRM/MANUFACTURER**

Blood Systems, Inc., Las Vegas, NV, by e-mail on February 12, 2010 and by letter dated March 17, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

Switzerland

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**PRODUCT**

Platelets. Recall # B-1543-10

**CODE**

Unit: W035210058676W

**RECALLING FIRM/MANUFACTURER**

Carter BloodCare, Bedford, TX, by telephone on February 19, 2010 and by letter dated March 23, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

TX

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**PRODUCT**

Recovered Plasma. Recall # B-1546-10

**CODE**

Unit: 53FJ09097

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by facsimile and electronic notification on February 1, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

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**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1548-10

**CODE**

Unit: 9403172

**RECALLING FIRM/MANUFACTURER**

LifeShare Community Blood Services, Elyria, OH, by letter dated March 1, 2010. Firm initiated recall is complete.

**REASON**

Blood product, which was not stored under continuous agitation and controlled temperature, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

OH

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**RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II**

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**PRODUCT**

Access Immunoassay Systems Accu Tnl Reagent Kit when used in conjunction with UniCel DxI Access Immunoassay Systems; Reagent Part Numbers: A78803 & 33340; Calibrator Part Number: 33345 The intended use: The Access AccuTnl assay is a paramagnetic particle, chemiluminescent

immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage. Cardiac Troponin I determination also aids in the risk stratification of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures. Recall # Z-1318-2010

**CODE**

Lot Numbers: 716707, 720541, 720542, 721451, 721452, 722677, 722678, 821024, 821025, 821515, 821663, 823314, 823523, 823524, 823850, 825783, 825784, 826258, 826259, 827876, 828479, 829974, 831218, 850000, 850003, 850004, 850005, 850010, 850011, 850013, 908322, 908323, 908917, 908918, 909803, 909804, 911338, 911339, 911748, 912628, 912629, 913131, 913132, 913265, 913274, 913500, 913821, 914632, 915132, 915417, 915670, 915850, 916720, 916721, 916721A, 917611, 918460 Note: These Lot Numbers represent all reagent lots released to field that could be used in conjunction with UniceL DxI Access Immunoassay Systems.

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Beckman Coulter Inc., Brea, CA, by letter dated February 5, 2010.

Manufacturer: Beckman Coulter, Inc., Chaska, MN. Firm initiated recall is ongoing.

**REASON**

The recall was initiated because Beckman Coulter has confirmed customer reports that different results have been obtained using the same patient samples on Access/Access 2 and UniCel DxI platforms. Values obtained with UniCel DxI systems have been demonstrated to have a positive bias compared to values obtained with Access or Access 2 systems.

**VOLUME OF PRODUCT IN COMMERCE**

196,071 kits

**DISTRIBUTION**

Nationwide and Canada

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**PRODUCT**

Elekta Synergy XVI The intended use: Radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner. Recall # Z-1411-2010

**CODE**

Units: 134351, 134524, 134723, 135003, 135013, 135015, 135020, 135022, 135023, 135024, 135025, 135028, 135035, 135036, 135037, 135038, 135042, 135046, 135047, 135055, 135056, 135058, 135061, 135062, 135063, 135068, 135071, 135072, 135073, 135076, 135078, 135079, 135081, 135085, 135087, 135090, 135093, 135096, 135100, 135101, 135103, 135104, 135105, 135110, 135111, 135113, 135118, 135119, 135121, 135122, 135124, 135125, 135126, 135133, 135142, 135144, 135150, 135151, 135157, 135158, 135163, 135164, 135167, 135168, 135170, 135172, 137173, 135175, 135177, 135181, 135182, 135184, 135189, 135191, 135190, 135192, 135195, 135196, 135199, 135200, 135206, 135207, 135208, 135209, 135210, 135211, 135215, 135216, 135225, 135226, 135227, 135230, 135233, 135235, 135237, 135241, 135247, 135251, 135256, 135258, 135259, 135262, 135265, 135267, 135271, 135272, 135273, 135274, 135277, 135278, 135284, 135285, 135287, 135288, 135291, 135292, 135296, 135298, 135300, 135303, 135305, 135306, 135313, 135316, 135323, 135324, 135326, 135328, 135331, 135332, 135334, 135335, 135336, 135337, 135340, 135341, 135343, 135346, 135347, 135348, 135351, 135352, 135353, 135355, 135356, 135359, 135361, 135367, 135368, 135382, 135383, 135384, 135389,

135391, 135393, 135394, 135412, 135413, 135420, 135446, 135455, 136125, 136126, 136127, 136176, 136244

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Elekta, Inc., Norcross, GA, by letters dated September 19, 2007, November 8, 2007, March 10, 2009, and April 29, 2009.

Manufacturer: Elekta Oncology Systems (Fmrl Philipps), Crawley, West Sussex, UK. Firm initiated recall is ongoing.

**REASON**

Firm became aware of a failure in the position detection system which could result in incorrect positioning of the detector in the longitudinal or lateral direction.

**VOLUME OF PRODUCT IN COMMERCE**

166 units

**DISTRIBUTION**

Nationwide, Canada, Mexico

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**PRODUCT**

Swift-Lock (TM) Anchor Accessory Kit, Directions For Use Model 1192, ANS, A St. Jude Medical Company. Product is intended to be used as an accessory to the leads component of ANS SCS systems, functioning to secure the lead to the fascia or interspinous/supraspinous ligament.

Recall # Z-1425-2010

**CODE**

All lots

**RECALLING FIRM/MANUFACTURER**

Advanced Neuromodulation Systems, Inc., Plano, TX, verbally on February 22, 2010, and by letter dated March 8, 2010, Firm initiated recall is ongoing.

**REASON**

Directions for Use of product incorrectly stated lead compatibility information.

**VOLUME OF PRODUCT IN COMMERCE**

1,120 units

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Unilect ECG Electrodes. Intended use: Cardiac monitoring. Model Number 4560M. Recall # Z-1431-2010

**CODE**

Lots: 706268, 708152, 709705, 711967, 713648, 713977, 714391, 714392, 714685, 714687

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: ConvaTec, Skillman, NJ, by visit on March 9, 2010 and by letter dated March 11, 2010.

Manufacturer: Techniko Medical Ltd. Bh21 6vs, Wimborne, UK. Firm initiated recall is ongoing.

**REASON**

In an emergency situation where defibrillation is necessary and electrodes are already in use, the electrodes may malfunction and incorrectly report lack of cardiac activity.

**VOLUME OF PRODUCT IN COMMERCE**

567,000 units (189 cases)

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Instruction for Use for Symphony Double Pumping Kit; the instructions were packaged with the following non-sterile single user accessory kits for use with Symphony breast pumps: a) Model 67023, Harmony to Symphony Conversion Kit; b) Model 67091, Lactina to Symphony Conversion Retail Kit; c) Model 67099, Symphony Retail Kit; d) Model 67099-06, Symphony Retail Kit - case of 6 kits; e) Model 67099NA, Symphony Retail Kit - case of 6 kits for national accounts. Recall # Z-1442-2010

**CODE**

Item #1908095, revision B 0909, contained in kits shipped between 10/23/09 and 02/02/2010

**RECALLING FIRM/MANUFACTURER**

Medela Inc., McHenry, IL, by letter dated March 12, 2010. Firm initiated recall is ongoing.

**REASON**

The non-sterile devices were erroneously packaged with instructions stating the devices are sterile and do not require cleaning before first use.

**VOLUME OF PRODUCT IN COMMERCE**

13,834 kits

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Peloris Rapid Tissue Processor; catalog number 26.0001 and 26.0005. Recall # Z-1551-2010

**CODE**

Serial numbers: 0260001B to 0260341B, 0260344B, 0260346B to 0260353B, and 0260356B to 0260366B

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Leica Microsystems, Inc., Bannockburn, IL, by letters dated February 9, 2010.  
Manufacturer: Leica Biosystems Melbourne Leica BSD International Pty Ltd, Mount Waverly, Australia. Firm initiated recall is ongoing.

**REASON**

Confusion during manually changing reagents, general users running unvalidated protocols, and wax valve leakage have contributed to tissue damage during processing, leading to rebiopsies.

**VOLUME OF PRODUCT IN COMMERCE**

574 units

**DISTRIBUTION**

Nationwide, Canada, Australia, Europe and Asia

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**PRODUCT**

Intramedullary Fixation Rod, common name Fibula Rod, labeled IM Rod System: a) Model # 40-0028-S; b) Model # 40-0029-S; and c) Model # 40-0031-S. Recall # Z-1552-2010

**CODE**

a) Lot # W65318, exp: 06/2015; b) Lot # W64072, exp: 06/2015; c) Lot # W65319 exp: 06/2015

**RECALLING FIRM/MANUFACTURER**



Acumed LLC, Hillsboro, OR, by telephone, followed by an e-mail, and a letter on August 21, 2008. Firm initiated recall is complete.

**REASON**

Products improperly handled after cleaning, prior to sanitation and may be contaminated with inorganic material.

**VOLUME OF PRODUCT IN COMMERCE**

36 units

**DISTRIBUTION**

MA, CA, NM, TX United Kingdom and South Africa

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**PRODUCT**

1) Boston Scientific TELIGEN, Implantable Cardiac Defibrillator, a) Models E102 and b) Models E110. Sterilized using ethylene oxide. The product is indicated for patients who are at risk for sudden cardiac death due to ventricular arrhythmias and may require pacing support. COGNIS devices also provide bi-ventricular pacing. Recall # Z-1553-2010;

2) Boston Scientific COGNIS CRT-D, Cardiac Resynchronization Therapy Defibrillator, Models: a) N118 and b) N119. Sterilized using ethylene oxide. The product is indicated for patients who are at risk for sudden cardiac death due to ventricular arrhythmias and may require pacing support. COGNIS devices also provide bi-ventricular pacing. Recall # Z-1554-2010;

3) Boston Scientific CONFIENT, Model E030, Implantable Cardioverter Defibrillator (ICD). The CONFIENT Implantable Cardioverter Defibrillator (ICDs) are designed to detect and terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) and provide bradycardia therapy (atrial and ventricular pacing). Therapies include both low- and high-energy shocks using either a biphasic or monophasic waveform. Sterilized using ethylene oxide. Recall # Z-1555-2010;

4) Boston Scientific LIVIAN Cardiac Resynchronization Therapy Defibrillator (CRT-D), models: a) H220, b) H225, c) H227, d) H229. The LIVIAN families of cardiac resynchronization therapy defibrillators (CRT-Ds), provide ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF), rhythms that are associated with sudden cardiac death (SCD). Cardiac resynchronization therapy is for the treatment of heart failure(HF) and uses biventricular electrical stimulation to synchronize ventricular contractions. Sterilized using ethylene oxide. Recall # Z-1556-2010;

5) VITALITY Implantable Cardioverter Defibrillator. Atrial and Ventricular Therapies. AVT, a) Model A155. VITALITY DS DR/VR, b) Models T125, c) T135), VITALITY 2 DR/VR, d) Models T165; e) T175 and VITALITY 2 EL DR/VR, f) Models T167 and g) T177 Implantable Cardioverter Defibrillator. The device serial numbers are only provided for devices subject to the retrieval. For model number with no serial numbers there were no non-implanted devices with domestic customers. Once the required BSC submissions and FDA reviews are completed, the BSCs distribution and implant restrictions will no longer apply. Model T127, no serial numbers will be retrieved. Recall # Z-1557-2010;

6) CONTAK RENEWAL 3 a) Models H170, Guidant CONTAK RENEWAL 3 HE b) Models H177; c) Model H179. Cardiac Resynchronization Therapy Defibrillator (CRT-D). These CRT-Ds provide ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF), rhythms that are associated with sudden cardiac death (SCD). Cardiac resynchronization therapy is for the treatment of heart failure (HF) and uses biventricular electrical stimulation to synchronize ventricular contractions. Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. Sterile EO. The device serial numbers are only provided for devices subject to the retrieval. For model number with no serial numbers there were no non-implanted devices with domestic customers. Once the required BSC submissions and FDA reviews are completed, the BSCs distribution and implant restrictions will no longer apply. Model H175, no serial numbers will be retrieved. Model H170. Recall # Z-1558-2010;

7) VENTAK PRIZM Automatic Implantable Cardioverter Defibrillator (AICD). DR, a) Model 1851, DR HE, b) Model 1853 and d) Model 1858, PRIZM VR HE, c) Model 1857, PRIZM 2 VR e) Model 1860 and PRIZM 2 DR f) Model 1861. The ICDs are designed to detect and terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) and provide bradycardia therapy (atrial and ventricular pacing). Therapies include both low- and high-energy shocks using either a biphasic or monophasic waveform. Bradycardia pacing, including adaptive-rate features is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy. The devices denoted with DR offer dual-chamber bradycardia features (atrial and/or ventricular pacing and sensing), and the devices denoted with VR offer single-chamber bradycardia features (ventricular pacing and sensing). Sterilized with gaseous ethylene oxide. The device serial numbers are only provided for devices subject to the retrieval. For model number with no serial numbers there were no non-implanted devices with domestic customers. Once the required BSC submissions and FDA reviews are completed, the BSCs distribution and implant restrictions will no longer apply. Model 1850, 1852, 1855 and 1856, no serial numbers will be retrieved. Recall # Z-1559-2010

**CODE**

1) a) Serial numbers: 010347, 241131, 242141, 242171, 242431, 242505, 242543, 242657, 242708, 243839, 243965, 244071, 244521, 244580, 244921, 244928, 245000, 245295, 245479, 245519, 245578, 245583, 245619, 245655, 246303, 246369, 246384, 246395, 246396, 246481, 246498, 246502, 246508, 246511, 246516, 246542, 246546, 246548, 246558, 246561, 246592, 246609, 246618, 246653, 246752, 246756, 246888, 246959, 247313, 247342, 247346, 247417, 247452, 247481, 247614, 247618, 247632, 247663, 247687, 247779, 247788, 247893, 248102, 248353, 248557, 248587, 248622, 248630, 248635, 248670, 248805, 248916, 248933, 248968, 248997, 249064, 249083, 249087, 249130, 249370, 249398, 249454, 249468, 249496, 249533, 249534, 249537, 249538, 249556, 249594, 249602, 249627, 249629, 249631, 249650, 249669, 249727, 249751, 249753, 249777, 249868, 249882, 249925, 249934, 249943, 249954, 249960, 250007, 250020, 250031, 250049, 250067, 250089, 250114, 250120, 250121, 250135, 250139, 250147, 250159, 250191, 250194, 250197, 250206, 250230, 250233, 250234, 250246, 250258, 250279, 250289, 250290, 250306, 250324, 250328, 250330, 250337, 250349, 250368, 250382, 250387, 250400, 250421, 250422, 250424, 250431, 250436, 250482, 250497, 250498, 250518, 250538, 250541, 250544, 250553, 250579, 250585, 250596, 250597, 250599, 250602, 250641, 250660, 250670, 250675, 250679, 250684, 250719, 250772, 250781, 250788, 250790, 250794, 250802,

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3) Serial numbers: 504800, 505054, 505073, 506067, 506886, 506961, 507219, 507236, 507255, 507268, 507292, 507304, 507332, 507372, 507381, 507388, 507412, 507424, 507446, 507448, 507449, 507454, 507467, 507527, 507538, 507577, 507594, 507600, 507607, 507614, 507618,

507625, 507728, 507742, 507757, 507785, 507829, 507840, 507882, 507898, 507903, 507904, 507923, 507940, 507943, 507944, 507952, 507960, 507963, 507966, 507984, 508001, 508008, 508059, 508130;

4) a) Serial numbers: 511302, 512322, 513553, 513555, 513592, 513617, 513637, 513638, 513641, 513653, 513741, 513876, 513883, 513886, 513888, 513906, 513940, 513951, 513954, 513988, 514010, 514029, 514033, 514041, 514044, 514047, 514060, 514065, 514070, 514080, 514105, 514107, 514121, 514129; b) Serial numbers: 562014, 562031, 562033, 562040, 562067, 562080, 562116, 562124, 562129, 562133; c) Serial numbers: 511024, 561060, 561618, 562179, 562439, 562789, 563298, 563319, 563323, 563342, 563350, 563366, 563391, 563395, 563400, 563411, 563470, 563484, 563532, 563535, 563547, 563589, 563608, 563615, 563616, 563624, 563662, 563714, 563771, 563785, 563799, 563801, 563804, 563820, 563823, 563824, 563825, 563829, 563831, 563832, 563833, 563840, 563845, 563846, 563847, 563852, 563853, 563854, 563855, 563908, 563918, 563934, 563957, 563962, 563967, 563970, 563972, 563976; d) Serial numbers: 560803, 560813, 560837, 560872, 560873, 560891, 560918, 560921, 560946, 560958, 560959, 560968, 560978, 560985, 561002, 561006, 561021, 561023, 561028, 561030, 561036, 561040, 561057, 561061, 561069, 561073, 561077, 561080, 561092, 561095, 561155, 561158, 561160;

5) a) Serial numbers 117091, 117093; b) Serial numbers: 124969, 125087, 125099, 125113, 125134, 125231, 125244, 125266, 125293, 125327, 125337, 125349, 125352, 125357, 125362, 125366, 125380, 125382, 125395, 125396, 125418, 125428, 125430; c) Serial numbers: 948527, 949918, 950739, 950750, 950765, 950768, 950774, 950781, 950795, 950824, 950838, 950851, 950852, 950868, 950869, 950870, 950871, 950881, 950893, 950895, 950902; d) Serial numbers: 140004, 140008, 141750, 141752, 142959, 143653, 146287, 146318, 146333, 146345, 146379, 146386, 146419, 146424, 146483, 146492, 146514, 146564, 146743, 146764, 146881, 146893, 146901, 147009, 147044, 147161, 147179, 147193, 147310, 147417, 147450, 147461, 147464, 147507, 147515, 147553, 147554, 147555, 147560, 147568, 147675, 147693, 147695, 147704, 147706, 147724; T167, e) Serial numbers: 115638, 116948, 117036, 117236, 117249, 117251, 117254, 117256, 117257, 118293, 118295; f) Serial numbers: 133117, 138081, 138506, 138630, 138657, 138672, 138676, 138834, 138842, 138904, 138935, 139150, 139157, 139179, 139246, 139299, 139336, 139353, 139850, 139979, 139998, 140016, 140017, 140022, 140217, 140243, 140331, 140340; g) Serial numbers: 116495, 116872, 117635, 117758, 117800, 117814, 117821, 118308, 118318, 118321, 118326, 118329, 118330;

6) a) Serial numbers: 367529, 367531, 367582, 367593; b) Serial number 286645; c) Serial number 115199;

7) a) Serial number: 301173; b) Serial number: 405161; c) Serial numbers: 701901, 705521, 705555, 705564, 705568, 705575, 705624, 705721, 705759, 705774; d) Serial numbers: 801463, 801487, 801489, 801505, 801511, 801512, 801517; e) Serial number 131043; ;f) Serial numbers 201166, 230949

#### **RECALLING FIRM/MANUFACTURER**

Recalling Firm: Boston Scientific CRM Corp., Saint Paul, MN, by press release dated March 15, 2010 and March 18, 2010 and by letter dated March 22, 2010.

Manufacturer: Guidant Ireland, Clomel, County Tipperary, Ireland. Firm initiated recall is ongoing.

#### **REASON**

Boston Scientific Corporation has stopped shipment and is retrieving unimplanted devices from US hospital shelves of all its implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) after determining that some manufacturing process changes were not submitted for approval to the US Food & Drug Administration.

**VOLUME OF PRODUCT IN COMMERCE**

2491 units

**DISTRIBUTION**

Nationwide

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**PRODUCT**

- 1) ConMed Goldline Hand Controlled With Needle Electrode, Rocker Switch, Safety Holster and 10 FT Cable, REF 130301A, Sterile R, Assembled in Mexico. Recall # Z-1562-2010;
- 2) ConMed Goldline Hand Controlled With Blade Electrode, Tip Cleaner, Rocker Switch, Safety Holster and 10 FT Cable, REF 130304A, Sterile R, Assembled in Mexico. Recall # Z-1563-2010;
- 3) ConMed Goldline Hand Controlled With Blade Electrode, Rocker Switch, Safety Holster and 10 FT Cable, REF 130307A, Sterile R, Assembled in Mexico. Recall # Z-1564-2010;
- 4) ConMed Goldline Hand Controlled With Blade Electrode, Rocker Switch, Safety Holster and 10 FT Cable, REF 130319A, Sterile R, Assembled in Mexico. Recall # Z-1565-2010;
- 5) ConMed Goldline Hand Controlled With Blade Electrode, Rocker Switch, Safety Holster and 15 FT Cable, REF 130327A, Sterile R, Assembled in Mexico. Recall # Z-1566-2010;
- 6) ConMed Goldline Hand Controlled With Blade Electrode, Rocker Switch, Safety Holster and 15 FT Cable, REF 130337A, Sterile R, Assembled in Mexico. Recall # Z-1567-2010;
- 7) ConMed Goldline Hand Controlled, Rocker Switch, Safety Holster and 10 FT Cable, Bulk, REF 130339A, Non-Sterile, Assembled in Mexico. Recall # Z-1568-2010;
- 8) ConMed Goldline Hand Controlled with UltraClean Blade Electrode, Rocker Switch, Safety Holster and 10 FT Cable, REF 131307A, Sterile R, Assembled in Mexico. Recall # Z-1569-2010;
- 9) ConMed Goldline Hand Controlled with UltraClean Blade Electrode, Rocker Switch, Safety Holster and 10 FT Cable, REF 131319A, Assembled in Mexico. Recall # Z-1570-2010;
- 10) ConMed Goldline Hand Controlled with UltraClean Blade Electrode, Rocker Switch, Safety Holster and 15 FT Cable, REF 131327A, Sterile R, Assembled in Mexico. Recall # Z-1571-2010;
- 11) ClearVac Goldline Rocker Switch with Blade Electrode, REF 60-6829-001A, Sterile R, Assembled in Mexico. Recall # Z-1572-2010;
- 12) ClearVac Goldline Rocker Switch with UltraClean Blade Electrode, REF 60-6829-005A, Sterile R, Assembled in Mexico. Recall # Z-1573-2010

**CODE**



Lot code range: 0903253 through 1002143

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: ConMed Electrosurgery, Centennial, CO, by letter on March 25, 2010.

Manufacturer: Conmed Inc., Chihuahua, Mexico. Firm initiated recall is ongoing.

**REASON**

Electrosurgical pencil may remain activated or self activate after power switch is released.

**VOLUME OF PRODUCT IN COMMERCE**

683,440 units (Nationwide), 114,350 units (Internationally)

**DISTRIBUTION**

Nationwide, Australia, Belgium, Canada, China, Dominican Republic, El Salvador, Japan, Korea, Mexico, Puerto Rico, Saudi Arabia, Spain, Taiwan

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**PRODUCT**

An Imaging device for medical procedures, to provide surgeons or operating room personnel the ability to capture still images and to record video during the surgical procedures in various file formats. Images can be transferred to external media. Product Name: SDC HD units and SDC HDi units Model Numbers: 240-050-888 and 240-050-888i. Recall # Z-1590-2010

**CODE**

Code: All SDC HD and SDC HDi units

**RECALLING FIRM/MANUFACTURER**

Stryker Endoscopy, San Jose, CA, by letter on October 23, 2009. Firm initiated recall is ongoing.

**REASON**

Video device is not able to assign the correct time/date stamp.

**VOLUME OF PRODUCT IN COMMERCE**

12,825 units

**DISTRIBUTION**

Nationwide and Internationally

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**PRODUCT**

VNS Therapy Demipulse Generator, a) Model 103 and VNS Therapy Demipulse Duo Generator, b) Model 104 VNS Therapy Programming System, c) Model 250 Version 7.0 and 7.1 Software.

Recall # Z-1591-2010

**CODE**

(version 7.0 or 7.1)

**RECALLING FIRM/MANUFACTURER**

Cyberonics, Inc., Houston, TX, by letter on April 6, 2010. Firm initiated recall is ongoing.

**REASON**

Battery life projection is inaccurate.

**VOLUME OF PRODUCT IN COMMERCE**

a) 8109 units; b) 1722 units; c) Programmers: 8891

**DISTRIBUTION**

Nationwide and Internationally

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**PRODUCT**

Polarus(R) Humeral Fixation System, size: 3.5mm x 25.0mm Cortical Screw, QTY 1, Ref: HCO3250-S. Intended use: Acumed intramedullary rods and screws are designed to provide fixation of humeral, forearm and fibula fractures while they heal. Recall # Z-1602-2010

**CODE**

Lot code 203214

**RECALLING FIRM/MANUFACTURER**

Acumed LLC, Hillsboro, OR, by telephone on May 18, 2009 and by e-mails and letters on May 19, 2009. Firm initiated recall is complete.

**REASON**

Mix-up of parts - Product labeled cortical bone screw actually contains Acutract fixation screw.

**VOLUME OF PRODUCT IN COMMERCE**

83 units

**DISTRIBUTION**

FL, GA, MI, MN, NY, TX, VA, United Kingdom, Herzeles, South Korea, South Africa, China, and Milan

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**PRODUCT**

Leksell GammaPlan Leksell GammaPlan is designed for use with the Leksell Gamma Knife manufactured by Elekta Instrument AB. the Leksell GammaPlan is intended to be used for planning the dosimetry of treatments in stereotactic radio surgery and stereotactic radiation therapy. It processes the inputs of the health professions (Neurosurgeons, Radiation therapists, Radiation Physicists) such that the desired radiation dose is provided by the Leksell Gamma Knife to a precisely defined target area within the cranium. Recall # Z-1604-2010

**CODE**

Units: 2UA7361354, SG50425266, CZC75037DN, SG42820297, CZC707499P, SG34220707, CZC7044FLP, CZC7053FQD, CZC71228QT, CZC7354BN3, CZC740298, SG43520759, SG43720546, SG50825766, 2UA7291VKX, 2UA7291VJ3, US19378673, CZC354BN1, 0703150004, SG23320693, SG24820187, SG52720065, SG31620624, CZC70906S3, CZC70906SB, 2UA7361359, SG52720070, SG44925633, CZC70906S5, CZC7053FQ6, CZC706326M, 2UA736135C, 2UA7291VHT, SG34420200, SG32520836, 2UA7291VHY, 2UA7150VYH, SG43720660, CZC7481Q3R, SG50425271, SG50825764, US68115508, SG52720067, SG34620630, 2UA7251YHM, SG60320067, SG5272066, SG20620611, 2UA73317NW, SG41720274, SG41720317, SG31360678, SG40920412, SG31020317, SG33620363, SG24820212, CZC707499Q, CZC74024P9, SG42520530, CZC07031CRQ, CZC07031CRX, CZC70906S6, CZC70906S7, CZC7044FLN, SG50425273, SG50927332

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Elekta, Inc., Norcross, GA, by Phase 1 - Important Notice and Technical Note #200 058 - "Accuracy problems in Leksell GammaPlan 8.0 image fusion", dated December 10, 2007 and Field Change Order #200 058, "Technical Note: Accuracy problems in Leksell Gamma Plan 8.0 image fusion", dated January 7, 2008 were sent to affected customers and all field service engineers as notification of the problem.

Manufacturer: Elekta Instrument AB, Stockholm, Sweden. Firm initiated recall is ongoing.

**REASON**

The precision of the calculation used to create the fused study in LGP 8.0 is too low and should not be used until the system is upgraded to LGP 8.2.

**VOLUME OF PRODUCT IN COMMERCE**

66 lots

**DISTRIBUTION**

Nationwide

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**PRODUCT**

Universal Flat Panel Yoke, a component of the Stryker Flat Panel Arm. The yoke is intended to hold a flat panel monitor. Catalog number: 0682400028. Recall # Z-1605-2010

**CODE**

Lot numbers: 1003, 1004, 1005, 1006

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Stryker Communications Corp., Flower Mound, TX, letter dated April 19, 2010.

Manufacturer: JLT Engineering Products, Ltd, Bridgeport, TX. Firm initiated recall is ongoing.

**REASON**

Some of the pitch shafts were not properly welded which results in the monitor becoming unlevel.

**VOLUME OF PRODUCT IN COMMERCE**

676 units

**DISTRIBUTION**

Nationwide, Canada, Australia, China (Hong Kong), Latin America (Mexico, Chile, Ecuador, Costa Rica)

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**PRODUCT**

1) EXXCEL Soft Standard Wall EPTFE Vascular Graft; D: 8 mm; L: 50 cm straight. Sterile Intended use: The Standard Wall EXXCEL and EXXCEL Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries and to provide vascular access. Wall Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries. UPN M002004810260. Recall # Z-1606-2010;

2) EXXCEL Soft Thin Wall EPTFE Vascular Graft; D: 8 mm; L: 50 cm straight. Sterile Intended use: The Standard Wall EXXCEL and EXXCEL Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries and to provide vascular access. Wall Soft ePTFE Vascular Grafts are designed to repair or replace peripheral arteries. UPN M002004948580. Recall # Z-1607-2010

**CODE**

1) Lot 11423751; Exp 12/2010;

2) Lot 11407455, Exp 12/2010

**RECALLING FIRM/MANUFACTURER**

Maquet Cardiovascular, LLC, Wayne, NJ, by letter dated March 23, 2010. Firm initiated recall is ongoing.

**REASON**

This is an expansion of Recall # Z-866-2010, adding an additional two lots to the recall of EXXCEL soft Stand Wall EPTFE Vascular Grafts due to a labeling mix up.

**VOLUME OF PRODUCT IN COMMERCE**

23 units

**DISTRIBUTION**

TX, NJ, SC, MO, ID, TN, FL, CA, PA, Canada and Germany

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**PRODUCT**

Coated VICRYL RAPIDE (polyglactin 910) Braided Coated Synthetic Absorbable Suture, Undyed.  
Intended use: Soft Tissue approximation. Recall # Z-1608-2010

**CODE**

Lot # mfg date Exp date VR496 ZE9CZME0 04-Jun-07 2012-05 VR944 ZE9GLZD0 05-Jun-07  
2012-05 VR932 ZE9HGDG0 06-Jun-07 2012-05 VR496 ZE9GHCE0 06-Jun-07 2012-05 VR844  
ZE9GSWE0 07-Jun-07 2012-05 VR845 ZE9HCMG0 07-Jun-07 2012-05 VR917 ZE9GWPD0 30-  
May-07 2012-05 VR496 ZE9HGGE0 12-Jun-07 2012-05 VR834 ZE9HPHG0 11-Jul-07 2012-05  
VR935 ZE9JGGE0 06-Jun-07 2012-05 VR493 ZE9JTSE0 15-Jun-07 2012-05 VR416 ZE9KHXC0  
22-Jun-07 2012-05 VR494 ZE9KLTE0 14-Jun-07 2012-05 VR417 ZE9JLQD0 06-Jun-07 2012-05  
VR496 ZE9JZTE0 27-Jun-07 2012-05 VR493 ZG9CSPE0 27-Jun-07 2012-06 VR497 ZE9KPLE0  
20-Jun-07 2012-05 VR496 ZE9KCGE0 25-Jun-07 2012-05 VR944 ZG9BJTD0 28-Jun-07 2012-06  
VR834 ZG9DHJG0 03-Jul-07 2012-06 VR496 ZG9CLZE0 26-Jun-07 2012-06 VR426  
ZG9CWJE0 26-Jun-07 2012-06 VR490 ZG9DMTD0 03-Jul-07 2012-06 VR945 ZG9DTKG0 29-  
Jun-07 2012-06 VR845 ZG9GDDG0 03-Jul-07 2012-06 VR496 ZG9DHPE0 03-Jul-07 2012-06  
VR835 ZG9GLMG0 29-Jun-07 2012-06 VR844 ZG9GJQE0 03-Jul-07 2012-06 VR931  
ZG9GJSH0 03-Jul-07 2012-06 VR932 ZG9HZLG0 03-Jul-07 2012-06 VR497 ZG9GZRE0 03-Jul-  
07 2012-06 VR944 ZG9GZSD0 29-Jun-07 2012-06 VR917 ZG9JBXD0 11-Jul-07 2012-06 VR945  
ZG9HQWG0 10-Jul-07 2012-06 VR497 ZG9JRBE0 11-Jul-07 2012-06 VR416 ZG9KHSC0 11-  
Jul-07 2012-06 VR493 ZG9JTSE0 12-Jul-07 2012-06

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Ethicon, Inc., Somerville, NJ, by letters dated April 20, 2010.

Manufacturer: Ethicon GmbH, Norderstedt, Germany. Firm initiated recall is ongoing.

**REASON**

Channels in the packaging seal that can lead to suture degradation and loss of packaging integrity.

**VOLUME OF PRODUCT IN COMMERCE**

118332 eaches to US distribution centers, 69,936 eaches to primary consignees

**DISTRIBUTION**

Nationwide, Austria, Belgium, Canada, Chile, China, Czech Republic, Egypt, Germany, Greece,  
Hong Kong, Hungary, Israel, Italy, Japan, Korea, Malaysia, Middle East, Netherlands Antilles,  
New Zealand, Poland, Portugal, Russia, Saudi Arabia, Slovenia, South Africa, Spain, Sweden,  
Switzerland, Turkey, United Arab Emirates, United Kingdom

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**PRODUCT**

Odyssey Intended use: Radiation treatment planning system. Recall # Z-1609-2010

**CODE**

Version 4.4 through 4.6

**RECALLING FIRM/MANUFACTURER**

PerMedics, Inc., San Bernardino, CA, by letter dated March 23, 2010. Firm initiated recall is ongoing.

**REASON**

Anomaly 1, Invalid Characters in Patient ID Error: Currently, Odyssey considers a valid ID to be comprised of numbers and/or letters. If a patient ID in a study contains a character other than a letter or number (including spaces). Odyssey removes the invalid character when moving it to a patient folder. Due to this, it is possible that two different patient studies could be listed within Odyssey for one patient. Anomaly 2, Odyssey Machine Library Error: The Odyssey Machine Library contains configuration formation for each treatment machine. mode, etc. Currently, if the

Machine Library contains treatment modes with two different collimator types (for example, jaws and cones), then it is possible for the software to use the incorrect collimator type when calculating dose. It was tested and confirmed that based on our records of the current customers' libraries, this anomaly will not occur. This anomaly can occur ONLY if the user modified the commissioned Machine Library without PerMedics' knowledge such that the treatment mode that uses circular cones is listed as the first mode in the Machine Library before the photon mode using jaws AND the mode using jaws is selected during planning. In this case, the software would automatically use the incorrect collimator type (cone) when calculating dose. Anomaly 3, Odyssey MLC Block Error: Odyssey allows the user to add an Odyssey MLC block (a virtual block) to move the MLC leaves automatically to cover a selected tissue region. When a virtual block is used, a block tray would not be expected in setup; however, Odyssey currently considers a block tray transmission factor when calculating dose with an Odyssey MLC block. The dose can be off' by as much as a tray factor, which is typically 2-5%, depending on beam energy. The use of the tray factor used is clearly indicated on the DICOM RT Plan and Odyssey report exported.

**VOLUME OF PRODUCT IN COMMERCE**

16 units

**DISTRIBUTION**

NY, GA, CA, MA, Brazil, Hungary, China, India, Italy, Mexico.

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**PRODUCT**

Newport e360 Ventilator The e360 Ventilator System is intended to provide continuous (endotracheal or tracheostomy [ET] tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric, and adult patients requiring tidal volumes equal to or greater than 20 milliliters (mL). The device is for use by prescription only. The intended environments include hospital, hospital-type, and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, emergency rooms, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing facilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility. Recall # Z-1617-2010

**CODE**

All serial numbers beginning with N093609XXXXX, N093610XXXXX, N093611XXXXX, and N093612XXXXX

**RECALLING FIRM/MANUFACTURER**

Newport Medical Instruments Inc., Costa Mesa, CA, by letter dated April 14, 2010. Firm initiated recall is ongoing.

**REASON**

The recall was initiated due to a recent increase in complaints related to the early failure of a low pressure transducer which is on Printed Circuit Board (PCB) 2104A in the Newport e360 ventilator. Ventilators manufactured between September and December 2009 are affected by this field correction. All affected ventilators require the replacement of the PCB2104A board to avoid early failure of this pressure transducer. The failure of the pressure transducer results in pressure or volume alarms where P1 cannot be calibrated correctly or in a Device Alert alarm associated with a P1 failure. In most cases, the failure is detected at power on but failures can occur during ventilation.

**VOLUME OF PRODUCT IN COMMERCE**

990 Units

**DISTRIBUTION**

Nationwide, Armenia, Bolivia, Brazil, Bulgaria, China, Colombia, Ecuador, Egypt, Greece, Hong Kong, India, Malaysia, Mauritius, Mexico, Nicaragua, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Russia, Saudi Arabia, Serbia, South Africa, Sri Lanka, Syria, Taiwan, Thailand, Tunisia, Turkey, UAE, Ukraine, Vietnam

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**PRODUCT**

HeartStart MRx Defibrillator Monitor, Model M3535A HeartStart MRx Defibrillator Monitor, Model M3536A The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician. Recall # Z-1618-2010

**CODE**

Serial Numbers: US00315427 US00321619 US00534669 US00536993 US00537058 US00537105 US00537109 US00537110 US00537123 US00537124 US00537126 US00537130 US00537132 US00537133 US00537143 US00537148 US00537149 US00537150 US00537151 US00537153 US00537155 US00537160 US00537161 US00537162 US00537165 US00537169 US00537170 US00537174 US00537180 US00537188 US00537191 US00537195 US00537196 US00537197 US00537201 US00537206 US00537207 US00537208 US00537211 US00537212 US00537213 US00537214 US00537217 US00537218 US00537222 US00537225 US00537226 US00537227 US00537228 US00537230 US00537231 US00537234 US00537235 US00537236 US00537237 US00537238 US00537239 US00537240 US00537241 US00537242 US00537246 US00537247 US00537248 US00537253 US00537255 US00537258 US00537259 US00537265 US00537268 US00537269 US00537273 US00537274 US00537275 US00537276 US00537277 US00537278 US00537282 US00537283 US00537289 US00537291 US00537292 US00537293 US00537294 US00537296 US00537297 US00537298 US00537300 US00537301 US00537302 US00537303 US00537304 US00537305 US00537307 US00537308 US00537309 US00537310 US00537311 US00537312 US00537313 US00537314 US00537315 US00537316 US00537317 US00537325 US00537326 US00537328 US00537330 US00537331 US00537332 US00537336 US00537337 US00537339 US00537340 US00537341 US00537342 US00537349 US00537350 US00537351 US00537354 US00537356 US00537357 US00537358 US00537359 US00537360 US00537361 US00537362 US00537363 US00537364 US00537365 US00537366 US00537367 US00537368 US00537369 US00537370 US00537373 US00537374 US00537375 US00537376 US00537377 US00537378 US00537379 US00537380 US00537381 US00537383 US00537384 US00537389 US00537390 US00537391 US00537446 US00537448 US00537449 US00537450 US00537451 US00537452 US00537453 US00537454 US00537456 US00537457 US00537458 US00537460 US00537461 US00537462 US00537463 US00537464 US00537465 US00537466 US00537467 US00537468 US00537469 US00537470 US00537471 US00537473 US00537474 US00537475 US00537476 US00537477 US00537478 US00537479 US00537480 US00537481 US00537482 US00537483 US00537484 US00537485 US00537486 US00537487 US00537488 US00537489 US00537490 US00537491 US00537492 US00537493 US00537494 US00537495 US00537497 US00537498 US00537499 US00537500 US00537502 US00537503 US00537504 US00537505 US00537506 US00537507 US00537508 US00537509 US00537510 US00537511 US00537512 US00537514 US00537515 US00537516 US00537518 US00537519 US00537520 US00537521 US00537522 US00537523 US00537524 US00537525 US00537526 US00537527 US00537528

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**RECALLING FIRM/MANUFACTURER**

Philips Healthcare Inc., Andover, MA, by letter dated April 7, 2009. Firm initiated recall is ongoing.

**REASON**

ECG signal processing chip may fail causing failure to deliver therapy in AED mode or the failure to indicate poor electrical contact (very high impedance) with the patient in Manual Defib mode.

**VOLUME OF PRODUCT IN COMMERCE**

1379 units

**DISTRIBUTION**

Nationwide, Canada, Argentina, Australia, Austria, Belgium, Brazil, China, Finland, France, Germany, Iceland, India, Ireland, Italy, Japan, Korea, Republic of Lithuania, Mexico, Netherlands, New Zealand, Norway, Poland, South Africa, Spain, Switzerland, Thailand, Trinidad, and Tobago, Ukraine, United Arab Emirates, United Kingdom

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**PRODUCT**

Inserter Wand Holder, Non-Sterile. Intended use: The Inserter Wand Holder serves two key functions. It firmly secures the Inserter Wand to prevent recoil during the NeuroPort Array

insertion process, and it facilitates precision alignment of the Inserter Wand with respect to the back of the NeuroPort Array just prior to pneumatic impulse insertion. Recall # Z-1619-2010  
**CODE**

Serial # 4273-0001 through 4273-0061

**RECALLING FIRM/MANUFACTURER**

I2s Micro Implantable Systems LLC, Salt Lake City, UT, by letter dated March 26, 2010. Firm initiated recall is ongoing.

**REASON**

Component of cranial array may not allow sufficient tightening to maintain inserter position.

**VOLUME OF PRODUCT IN COMMERCE**

22 units

**DISTRIBUTION**

Nationwide

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**PRODUCT**

1) Bausch & Lomb Millennium Microsurgical System Vit Enhancer (MVE). The MVE provides a pneumatic pulse train capable of driving a Vitreous Cutter at cutting rates up to 2500 cuts per minute. It is intended to be used for removal of vitreous or other intraocular tissue. Recall # Z-1662-2010;

2) Bausch & Lomb Millennium Microsurgical System Bausch & Lomb Millennium Microsurgical System is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, irrigation/aspiration, bipolar and photo coagulation, vitrectomy, viscous fluid injection/removal, and air/fluid exchange operations. Recall # Z-1663-2010;

3) Bausch & Lomb Stellaris Vision Enhancement System Bausch & Lomb Millennium Microsurgical System is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, irrigation/aspiration, bipolar and photo coagulation, vitrectomy, viscous fluid injection/removal, and air/fluid exchange operations. Recall # Z-1664-2010

**CODE**

All devices manufactured since 2004

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Bausch & Lomb Inc., Rochester, NY, by letter dated October 19, 2009.

Manufacturer: Bausch & Lomb Inc., Saint Louis, MO. Firm initiated recall is ongoing.

**REASON**

The AC power cords used on these products are subject to an FDA Alert -- Safety Investigation of Certain Medical Device Power Cords: Initial Communication.

**VOLUME OF PRODUCT IN COMMERCE**

Unknown

**DISTRIBUTION**

Nationwide, Venezuela, India, Trinidad and Tobago, Colombia, Sri Lanka, Hong Kong, Vietnam, and Peru

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**PRODUCT**

Responder 2000 Defibrillator/Monitor Models: 2025653, 2026109, and 2026114. Intended use: The Responder 2000 is indicated for the termination of certain fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and in relatively stable patients, ventricular tachycardia. The semi-automatic advisory mode is for use in cardiac arrest in patients of at least 8 years of age. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm. The 3-lead and 5-lead ECG monitoring allows for identification of interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate. The Responder 2000 noninvasive pacing as a therapy is indicated for patients with symptomatic bradycardia or asystole. The pulse oximetry is intended for the continuous external monitoring of arterial oxygen saturation and pulse rate and is indicated for use in any patient who is at risk of developing hypoxemia. MODELS: 2025653, 2026109, AND 2026114. The model numbers identify different AED configurations: MODEL 2025653 is the basic model; MODEL 2026109 is the basic model with pacing; and MODEL 2026114 is the basic model with pacing and SpO2 (oxygen saturation measured by pulse oximetry). OPERATOR'S MANUAL PART NUMBERS: (the 3 digit number at the end identifies the language in which the manual is written. Regardless of language the manuals are identical in content.) 2026116-001, 2026116-004, 2026116-005, 2026116-008, 2026116-010, 2026116-011, 2026116-012, 2026116-013, 2026116-014, 2026116-015, 2026116-016, 2026116-019, 2026116-022, 2026116-024, 2026116-025, 2026116-026, 2026116-033, AND 2026116-044. Recall # Z-1683-2010

**CODE**

Serial Numbers: 3100032, 3100033, 3100035, 3100036, 3200074, 3200075, 3200094, 3200107, 3200111, 3200112, 3200113, 3200114, 3200115, 3200116, 3200117, 3200118, 3200119, 3200120, 3200121, 3200122, 3200123, 3200124, 3200125, 3200126, 3200127, 3200128, 3200129, 3200130, 3200131, 3200132, 3200133, 3200134, 3200135, 3200136, 3200137, 3200138, 3200139, 3200140, 3200141, 3200142, 3200143, 3200144, 3200145, 3200148, 3200149, 3200150, 3200151, 3200152, 3200153, 3200154, 3200155, 3200156, 3200157, 3200158, 3200159, 3200160, 3200161, 3200162, 3200163, 3200164, 3200165, 3200166, 3200167, 3200168, 3200169, 3200170, 3200171, 3200172, 3200173, 3200174, 3200175, 3200176, 3200177, 3200178, 3200179, 3200180, 3200181, 3200182, 3200183, 3200184, 3200185, 3200186, 3200187, 3200188, 3200189, 3200191, 3200192, 3200193, 3200194, 3200195, 3200196, 3200197, 3200198, 3200199, 3200200, 3200201, 3200202, 3200203, 3200206, 3200207, 3200208, 3200209, 3200210, 3200211, 3200212, 3200213, 3200215, 3200216, 3200217, 3200219, 3200220, 3200221, 3200222, 3200223, 3200224, 3200225, 3200226, 3200227, 3200228, 3200229, 3200230, 3200231, 3200232, 3200233, 3200234, 3200235, 3200236, 3200237, 3200238, 3200239, 3200240, 3200241, 3200242, 3200243, 3200244, 3200245, 3200247, 3200248, 3200249, 3200250, 3200251, 3200252, 3200253, 3200254, 3200255, 3200256, 3200257, 3200259, 3200260, 3200261, 3200262, 3200263, 3200265, 3200266, 3200267, 3200268, 3200269, 3200271, 3200276, 3200277, 3200278, 3200282, 3200285, 3200309, 3200312, 3200318, 3200320, 3200321, 3200322, 3200323, 3200324, 3200325, 3200326, 3200327, 3200328, 3200329, 3200330, 3200331, 3200332, 3200335, 3200336, 3200337, 3200338, 3200339, 3200340, 3200343, 3200344, 3200345, 3200346, 3200347, 3200349, 3200351, 3200352, 3200353, 3200354, 3200358, 3200362, 3200363, 3200364, 3200366, 3200367, 3200368, 3200370, 3200371, 3200372, 3200373, 3200375, 3200376, 3200377, 3200378, 3200379, 3200380, 3200381, 3200382, 3200383, 3200384, 3200385, 3200386, 3200388, 3200389, 3200392, 3200393, 3200394, 3200395, 3200398, 3200399, 3200400, 3200401, 3200402, 3200404, 3200405, 3200406, 3200407, 3200408, 3200411, 3200412, 3200413, 3200416,





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**RECALLING FIRM/MANUFACTURER**

Cardiac Science Corp., Bothell, WA, by letter dated October 15, 2009. Firm initiated recall is ongoing.

**REASON**

The Operators Manual may not have adequate information to clearly explain some device behaviors. Pressing and holding down the Charge or Shock button on the Responder 2000 for more than 5 seconds causes a "Button Stuck" error. With the "Button Stuck" error, the device will automatically exit Manual mode and enter Monitor mode. The user cannot apply therapy while the device is in Monitor mode.

**VOLUME OF PRODUCT IN COMMERCE**

1838 units

**DISTRIBUTION**

Nationwide, Australia, Brazil, Columbia, Costa Rica, Denmark, Finland, France, Germany, Italy, Korea, Mexico, New Zealand, Panama, Paraguay, Peru, Singapore, South Africa, Spain, and Uruguay

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**PRODUCT**

The Alternans Sensor Kit Assembly is a sealed kit that contains the components necessary for conducting a Microvolt Twave Alternans test. Recall # Z-1776-2010

**CODE**

Lot # 550312 Lot # 5229 Lot # 700104 Lot # 5734 Lot # 700362 Lot # 6343 Lot # 700383 Lot # 6433 Lot # 700585 Lot # 6853 Lot # 700589 Lot # 6966 Lot # 700649 Lot # 7178

**RECALLING FIRM/MANUFACTURER**



Cambridge Heart, Inc., Tewksbury, MA, by letter dated April 23, 2010. Firm initiated recall is ongoing.

**REASON**

Some kits contained a component with expiration date prior to the date of expiry on the outside of the kit. The user receives feedback of potential unreliable results at several stages during the test process, so any risk of unreliable results is very low.

**VOLUME OF PRODUCT IN COMMERCE**

2,750

**DISTRIBUTION**

Nationwide

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**PRODUCT**

DATEX-Ohmeda Tusat Pulse Oximeter and Accessories, Model 3500. Recall # Z-1814-2010

**CODE**

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FCCH00685 FCD06170016SA FCD06170075SA FCD06360001SA FCD06360011SA  
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FCC06340124SA FCC07180103SA FCC07180104SA FCC07440025SA FCC07450016SA  
FCCJ00632 FCCJ00639 FCC06120017SA FCC06120051SA FCC06120069SA FCC06120092SA

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: GE Healthcare, LLC, Waukesha, WI, by letter dated April 22, 2010.

Manufacturer: GE Healthcare Finland Oy, Helsinki, Finland. Firm initiated recall is ongoing.

**REASON**

GE Healthcare has recently become aware that the TruSat Pulse Oximeter with external power supply does not comply with current safety standards. It is possible that the external power supply could leak electrical current. This current could cause third degree burns or an abnormal heart rhythm that, if untreated, could lead to death.

**VOLUME OF PRODUCT IN COMMERCE**

28,442 units

**DISTRIBUTION**

Nationwide and Internationally

**RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS III**

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**PRODUCT**

Pelton & Crane Spirit 3000 Dental Chair. The intended use of this device is for properly positioning patients to perform dental procedures. Catalog number: 3003, Model number: SP30.  
Recall # Z-1311-2010

**CODE**

Chair Serial #14736

**RECALLING FIRM/MANUFACTURER**

Pelton & Crane Co., Charlotte, NC, by letter dated February 9, 2010. Firm initiated recall is ongoing.

**REASON**

The Dental Chair lacks a valid Device History Record.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

Nationwide

**RECALLS AND FIELD CORRECTIONS: VETERINARY – CLASS I**

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**PRODUCT**

1) Response products Advanced Cetyl M Joint Action Formula For Dogs, With Cetyl Myristoleate, packaged in 120-tablet bottles (12/case) and 360-tablet bottles (6/case). Recall # V-065-2010;

2) VPL Harmonease Chewable Tablets, packaged in 30-tablet bottles, 12/case. Recall # V-066-2010

**CODE**

1) Lot numbers 1210903 and 0128010;

2) Lot number 1210908

**RECALLING FIRM/MANUFACTURER**

Tab's Limited, St. Joseph, MO, by telephone on April 7, 2010 and e-mail letter on April 8, 2010. Firm initiated recall is ongoing.

**REASON**

The product was manufactured using hydrolyzed vegetable protein recalled by Basic Food Flavors, Inc. because it has the potential to be contaminated with *Salmonella*.

**VOLUME OF PRODUCT IN COMMERCE**

251/12/120-tablet bottles/case and 794/6/360-tablet bottles/case Cetyl M; and 250/12/30-tablet bottle case Harmonease

**DISTRIBUTION**

NE, IA

**END OF ENFORCEMENT REPORT FOR JUNE 23, 2010**

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