Class 2 Device Recall CDI 500 Monitor

Class 2 Device Recall CDI 500 Monitor

See Related Information[22]

Date Initiated by Firm	February 03, 2012
Date Posted	April 06, 2012
Recall Status[1]	Terminated [3] on August 29, 2013
Recall Number	Z-1380-2012
Recall Event ID	60152[23]
510(K)Number	K972962[24]
Product Classification	Monitor, blood-gas, on-line, cardiopulmonary bypass[25] - **Product Code** DRY[26]
Product	CDI Blood Parameter Monitoring System 500, 500AV. Intended for use during cardiopulmonary bypass procedures.
Code Information	500AV CDI Blood Parameter Monitoring System 500 with Arterial and Venous blood parameter modules: 1192, 1193, 1355, 1356, 1420, 1423, 1464, 1465, 1467, 1468, 1483, 1504, 1521-1524, 1526, 1527, 1529, 1530, 1602-1604, 1606, 1662, 2023, 2035, 2102-2107, 2800, 2901, 2902, 3131-3135, 3261, 3262, 4132, 5330-5333, 5338-5340, and 5579.
FEI Number	1828100
Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor MI 48103-9586
For Additional Information Contact	734-741-6173
Manufacturer Reason for Recall	Replacement of the SBC batteries (system batteries) should be managed as "routine maintenance" instead of as an in-house Service Procedure because some systems may be relying on batteries beyond their useful life.
FDA Determined Cause [2]	Labeling design
Action	On 2/3/12 all consignees received an URGENT MEDICAL DEVICE RECALL letter via Federal Express. The letter described the reason for the recall, identified the affected product population, what to do in the event of a failure, the potential hazard, and correction. Terumo CVS will update the Operator's Manual for the CDI 500 with instructions to replace the battery within its useful life. Users are to review the notice and ensure that all users are made aware of the issue. In addition, the Customer Response Form should be completed and returned. Users can contact their local Terumo Cardiovascular Systems representative or call 1-800-521-2818 with questions or concerns, to check the last time system batteries were replaced, or to schedule maintenance for systems approaching 10 years.
Quantity in Commerce	3,829 units

Distribution	Worldwide Distribution -- USA, including the states of AK, AL, AR, AZ, CA, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, PR, SC, SD, TN, TX, UT, WV, WA, and WI and the countries of Japan, Germany, Barbados, Saudi Arabia, Columbia, Uruguay, Ecuador, Trinidad, Costa Rica, Paraguay, Panama, Belgium, Jordan, Libya, Mexico, Brazil, Honduras, Canada, Korea, Dominica Republic, El Salvador, Guatemala, Vietnam, Chile, Hong Kong, United Arab Emirates, Singapore, Australia, Malaysia, Taiwan, Philippines, Mexico, Thailand, Vietnam, and South Africa.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29].

510(K) Database	510(K)s with Product Code = DRY[30]

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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

29. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
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22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=60152
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