Class 2 Device Recall Terumo HX2 Temperature Management System

See Related Information[22]

Class 2 Device Recall Terumo HX2 Temperature Management System

Date Initiated by Firm	April 16, 2021
Create Date	June 04, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-1789-2021
Recall Event ID	87834[23]
510(K)Number	K071521[24]
Product Classification	Controller, temperature, cardiopulmonary bypass[25] - **Product Code** DWC[26]
Product	The Terumo HX2 Temperature Management System provides temperature control of two independent water circuits that directly controls the temperature of patient blood and cardioplegia solution during cardiovascular surgery. The system consists of a water tank, circulating pumps, heater manifolds, mercury free temperature sensors, water detectors, mixing valves and a tank divider which is provided to partition the tank into two separate channels (Left and Right). The system has the capacity to circulate water at a rate of up to 6.5 gal./min (25 L/min) with no load connected. The system is capable of heating and cooling for a single channel or for both channels. Device Name / Model Number: HX2 Temperature Management System (P/N 809810) Catalog Number: 809810
Code Information	All lot numbers distributed from 05/02/1985 thru 06/10/2015
Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corporation 6200 Jackson Rd Ann Arbor MI 48103-9586
For Additional Information Contact	Mary Swift 734-741-6056
Manufacturer Reason for Recall	Terumo CVS has been unable to validate a cleaning protocol to satisfy current regulatory concerns and expectations. As a result, an updated cleaning protocol will not be developed by Terumo CVS and it has been determined that the

	best course of action is for users to discontinue use of and dispose of HX2, TCM I and TCM II devices.
FDA Determined Cause [2]	Device Design
Action	On 04/30/2021, Terumo issued an Urgent Medical Device Removal notice to customer via letter notifying users to discontinue the use of and dispose of HX2, TCM I and TCM II devices. Customers were instructed to confirm receipt of this communication by completing and returning the attached Customer Response Form as indicated on the form. For questions contact Terumo CVS Customer Service: 1-800-521-2818.
Quantity in Commerce	75 devices
Distribution	Domestic: Foreign: Australia, Belgium, Canada, Chile, China, Colombia, Dominican Republic, England, France, Germany, Greece, Hong Kong, India, Indonesia, Iran, Israel, Italy, Japan, Korea, Malaysia, Mexico, Netherlands, New Zealand, Norway, Philippines, Russia, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, UNITED ARAB EMIRATES (UAE), Vietnam
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] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = DWC and Original Applicant = TERUMO CARDIOVASCULAR SYSTEMS CORP.[29]

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=87834
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K071521
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DWC
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DWC&knumber=&applicant=TERUMO%20CARDIOVASCULAR%20SYSTEMS%20CORP%2E

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=87834
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K071521
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26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DWC
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28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
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