Class 2 Device Recall Sarns TCM II

Class 2 Device Recall Sarns TCM II See Related Information 22

Date Initiated by Firm	April 16, 2021
Create Date	June 04, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-1791-2021
Recall Event ID	87834[23]
510(K)Number	K883603[24]
Product Classification	Controller, temperature, cardiopulmonary bypass[25] - **Product Code** DWC[26]
Product	The Sarns TCM II (system) is a source of temperature-controlled water for blood heat exchangers used in an extracorporeal circuit and for blankets to externally heat or cool the patient. It also freezes water for an ice supply, monitors temperatures in the patient and extracorporeal circuit, and allows gradient rewarming relative to a venous blood temperature. The Sarns" TCM II also features a Cardioplegia System which will supply cooling water for cardioplegia. Device Name / Model Number: TCM II, with Cardioplegia, 110V/60Hz (P/N 164925) TCM II, without Cardioplegia, 110V/60Hz (P/N 164930) TCM II, with Cardioplegia, 220V/50Hz (P/N 164935) TCM II, without Cardioplegia, 220V/50Hz (P/N 164940) TCM (P/N 15747) Catalog Number: 4415, 164925, 164930, 164935, 15747
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	995 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 = 3M HEALTH CARE, SARNS[29]

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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
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DWC&knumber=&applicant=3M%20HEALTH%20CARE%2C%20SARNS

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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
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28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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