Class 2 Device Recall Sarns TCM II

Date Initiated by Firm: April 16, 2021
Create Date: June 04, 2021
Recall Status: Open, Classified
Recall Number: Z-1791-2021
Recall Event ID: 87834
510(K) Number: K883603

Product Classification: Controller, temperature, cardiopulmonary bypass, Product Code DWC

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
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

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.

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