Class 2 Device Recall Terumo Advanced Perfusion System 1 Flow Module

Date Initiated by Firm: January 19, 2018
Create Date: April 20, 2018
Recall Status: Open, Classified
Recall Number: Z-1478-2018
Recall Event ID: 79624
510(K) Number: K172220
Product Classification: Console, heart-lung machine, cardiopulmonary bypass - Product Code DTQ
Product: Flowmeter Module (accessory to Terumo Advanced Perfusion System 1).

Provides the interface between the flow sensor and the system.

Code Information: Catalog #: 802018, Serial #: 01662, 01672, 01680, 01681, 01682, 01683, and 01687, UDI: 00865799000987
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: Inaccurate flow readings. Depending on the degree of inaccuracy, this issue may not be easy for the user to detect during setup or use (for example, following a Flow Probe relocation or manipulation).

FDA Determined Cause: Employee error

Action: The firm notified customers via phone alerting them of this affected device, issue, potential hazard, correction, and instructions. The communication also included scheduling an expedited service call for a Field Service Technician to replace the affected Flowmeter Module with a corrected Flowmeter Module. When necessary to avoid delaying or cancelling life-sustaining surgery, users can continue to use the Flowmeter Module while awaiting replacement. Once the issue is recognized by the user, if a replacement Flowmeter Module is available, replacement and reassignment of safety connections of the Flowmeter Module can be accomplished in less than 15 seconds. In the event that a replacement Flowmeter Module is not available, a less common mitigation is the use of a back-up stand-alone centrifugal pump or a stand-alone ultrasonic flowmeter system to provide flow data. Customers should receive a copy of the Urgent Medical Device Recall phone script by e-mail along with a Customer Response Form. The e-mail should be reviewed, and the form completed and returned as indicated. Questions or concerns can be directed Terumo CVS Customer Service at 1-800-521-2818.

Quantity in Commerce: 7

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=162847
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