See Related Information[22]

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[1]	Open[3], Classified
Recall Number	Z-1478-2018
Recall Event ID	79624[23]
510(K)Number	K172220[24]
Product Classification	Console, heart-lung machine, cardiopulmonary bypass[25] - **Product Code** DTQ[26]
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: 00886799000687.
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	Inaccurrate 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 [2]	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