DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	12/06/2005 - 12/09/2005 FEI NUMBER 1828100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark A. Sutter, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Terumo Cardiovascular Systems Corporation	6200 Jackson Rd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ann Arbor, MI 48103-9586	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, of the seventeen Medical Device Reports that were reviewed, approximately fourteen of the device malfunction or serious injury reports were not reported within 30 days of receiving or becoming aware of the incident. Examples include:

MDR	Date Informed	Date Reported	Days to Report
1828100-2005-00072	5/31/05	8/20/05	80 Days
1828100-2005-00043	4/30/05	7/6/05	67 Days
1828100-2005-00032	4/5/05	6/8/05	64 Days
1828100-2005-00035	5/5/05	6/18/05	44 Days

Annotation: Promised to correct within 30 days.

OBSERVATION 2

Complaints involving the possible failure of a device to meet any of its specifications were not reviewed and evaluated where necessary.

Specifically, one of seventeen complaints evaluated was incomplete. Product Performance Report #234 was received on 7/18/05 for a 100/120V AC APS Platform System. The complaint states that the customer turned the speed down manually but could not turn the speed back up manually. ~~The pump is only able to be controlled from the screen.~~ The investigation determined root cause to be the (b)(4) [redacted] Neither the ~~the~~ firm's investigation or corrective action plan included an evaluation concerning the effects that the failed T-filters could have on the existing product in the field.

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OBSERVATION 3

Employees have not been adequately trained.

Specifically, employee training records reviewed during the current inspection did not include adequate training. Two of (b)(4) employee training records were incomplete in that:

- Employee (b)(6) Corporate PPR Coordinator was participating in on -the-job training for Medical Device Reporting but had not received training on procedures "QSP-Medical Device Vigilance, Correction, Removal and Recall" document #78-8067-8512-3, Revision K or "MDR and Vigilance Reporting Decision Record" document #78-8067-3732-2, Revision P.
- **Procedure QSP-Associate Training System, document #801603, Revision C is incomplete, in that it does not require training on the following Quality System requirements:** Employee (b)(6) Field Service Representative has not received training on the "Quality Manual" document #78-8066-8306-2, Revision N, Work Instruction Form "Quality Policy Orientation" document #810387, Revision B or "Annual Quality System Training" document #813093, Revision A.

Annotation: Promised to correct within 30 days.

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

William D. Tingley

William D. Tingley, Investigator

Benjamin J. Smith

Benjamin J. Smith, Investigator

SEE REVERSE OF THIS PAGE	This is a modified document.	DATE ISSUED 12/09/2005