SEP 1 9 2002

K022857

SECTION II 510(k) SUMMARY AND CERTIFICATION

510(k) Summary

Pump Tubing with X-Coating

Submitter Information:

Name and Address:
Terumo Cardiovascular Systems Corporation
28 Howe Street
Ashland, MA 01721

Contact Person:
Kazuhito Inoue
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Telephone: 1-800-283-7866, Ext. 7001

Date of Preparation: August 21, 2000

Device Names:

Proprietary Name: Pump Tubing with X-Coating
Common Name: Pump Tubing
Classification Name: Tubing, Pump, Cardiopulmonary Bypass

Predicate Device:

The Pump Tubing with X-Coating that is the subject of this premarket notification is substantially equivalent in intended use, materials, design, technology and principles of operation, and performance to the uncoated Pump Tubing (K993189).

Intended Use:

The Cardiopulmonary Bypass Pump Tubing with X-Coating is intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary bypass procedures.

Principles of Operation and Technology:

The pump tubing that is the subject of this premarket notification is used in a pump head and becomes cyclically compressed by the pump to cause the blood to flow through the bypass circuit.

Design and Materials:

Each size of the Pump Tubing with X-Coating that is included in this submission is comprised of polyvinyl chloride (PVC).

The tubing size transitions in the raceway section. The specifications are as follows:

Tubing Identification	Pump Tubing with X-Coating				
	End		Mid		Durom.
	I.D.	O.D.	I.D.	O.D.	
Tubing number 1	.25"	.375"	.375"	.50"	68
Tubing number 2	.375"	.561"	.50"	.686"	68

Each tubing size is coated with a biocompatible polymer coating (X-Coating) that is intended to reduce the adhesion of platelets to the internal surface of the tubes as blood flows through the circuit.

Performance Evaluations:

The performance of the Pump Tubing with X-Coating submitted in this premarket notification is substantially equivalent to the performance of the uncoated pump tubing. The following tests were conducted to demonstrate equivalence in performance:

- Dimensional/Visual Analysis
- Leakage and Mechanical Integrity Testing
- Pull Force Testing
- 6-hour Circulation Testing
  - Flow Rate
  - Durability/Spallation
  - Thrombus Formation (Visual)
  - Effects Upon Cellular Components (Hemolysis)

Substantial Equivalence Comparison:

The Pump Tubing with X-Coating is substantially equivalent to the uncoated pump tubing as follows:

- Intended Use: Both the Pump Tubing with X-Coating and the uncoated pump tubing are intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary procedures.

- Principles of Operation and Technology: The Pump Tubing with X-Coating and the uncoated pump tubing each utilize the same technologies in the operation of the devices. They are each used in a pump head and become cyclically compressed by the pump rollers to cause the blood to flow through the bypass circuit.

- Design and Materials: The design and the materials of the Pump Tubing with X-Coating and the uncoated tubing are exactly the same with the exception of the X-Coating polymer that is applied to the coated tubing.

- Performance: Comparisons of the performance of the Pump Tubing with X-Coating and the uncoated pump tubing were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the two devices.

Substantial Equivalence Summary:
In summary, the Pump Tubing with X-Coating and the uncoated tubing are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo Cardiovascular Systems Corporation (TCVS) conducted the biocompatibility studies recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- TCVS conducted studies for materials characterization, including physico-chemical profiles.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

Conclusion:
In summary, the Pump Tubing with X-Coating is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate uncoated tubing (K993189).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2002

Terumo Medical Corporation
c/o Mr. Kazuhito Inoue
Regulatory Affairs
125 Blue Ball Road
Elkton, Maryland 21921

Re: K022857
Trade Name: Pump Tubing with X-Coating
Regulation Number: 21 CFR 870.4390
Regulation Name: Cardiopulmonary Bypass Pump Tubing
Regulatory Class: Class II (two)
Product Code: DWE
Dated: August 26, 2002
Received: August 28, 2002

Dear Mr. Inoue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **Pump Tubing with X-coating**

Indications For Use:

The Cardiopulmonary Bypass Pump Tubing with X-Coating is intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary bypass procedures.

The *tubing* is intended for use in procedures lasting up to 6-hours in duration.

Kazuhito Inoue
Regulatory Affairs
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022854

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)