JAN 2 2 2002

K013578

Pump Tubing

Submitter Information:

Name and Address:
Olson Medical Sales, Inc.
28 Howe Street
Ashland, MA 01721

Contact Person:
Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: October 24, 2000

Device Names:

Proprietary Name: Pump Tubing
Common Name: Pump Tubing
Classification Name: Tubing, Pump, Cardiopulmonary Bypass

Predicate Device:

The Pump Tubing that is the subject of this premarket notification is substantially equivalent to the predicate device; Pexco brand PVC tubing, which is legally marketed and has been in interstate commerce prior to May 28, 1976. As such, the predicate tubing is considered to have *pre-amendment* status.

Intended Use:

The Pump Tubing is intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary bypass procedures. The tubing is also intended to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit.

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

Principles of Operation and Technology:

The pump tubing that is the subject of this premarket notification may be used in a pump head and becomes cyclically compressed by the pump to cause the blood to flow through the bypass circuit. When not routed through the pump head, the tubing provides a conduit for the flow of blood throughout the circuit.

Design and Materials:
Each of the three sizes of the Pump Tubing that is included in this submission is comprised of polyvinyl chloride (PVC). The tubing ranges in size from a ¼" inside diameter to ½" in diameter. The durometer measurement is Shore A-68.

Performance Evaluations:
The performance of the Plastron Pump Tubing submitted in this premarket notification is substantially equivalent to the performance of the Pexco PVC pump tubing. The following tests were conducted to demonstrate equivalence in performance:

- Dimensional Analysis
- Leakage Testing/Structural Integrity
- Effects Upon Cellular Components (Hemolysis)
- Flow Rate Testing
- Durability Testing
- Spallation Evaluation
- Thrombus Formation (Visual)

Substantial Equivalence Comparison:
The *Plastron* Pump Tubing is substantially equivalent to the *Pexco* pump tubing as follows:

- Intended Use: Both the *Plastron* Pump Tubing and the predicate *Pexco* pump tubing are intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary procedures. Each tubing is also intended to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit.

- Principles of Operation and Technology: The *Plastron* Pump Tubing and the predicate *Pexco* 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 to cause the blood to flow through the bypass circuit. When not routed through the pump head, the tubing provides a conduit for the flow of blood throughout the circuit.

- Design and Materials: The design of the *Plastron* Pump Tubing and the predicate *Pexco* tubing are the same; and are comprised of the same *type* of material, i.e., polyvinyl chloride.

- Performance: Comparisons of the performance of the *Plastron* Pump Tubing and the predicate *Pexco* 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 Plastron Pump Tubing and the *Pexco* pump 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).
- Olson Medical Sales, Inc. 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.

Conclusion:
In summary, the *Plastron* Pump Tubing is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate *Pexco* tubing, which has *preamendment* status (is legally marketed and was in interstate commerce prior to May 28, 1976).

Olson Medical Sale's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Ms. Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K013578
Trade Name: Pump Tubing
Regulation Number: 21 CFR 870.4390
Regulation Name: Cardiopulmonary Bypass Pump Tubing
Regulatory Class: Class II (two)
Product Code: DWE
Dated: October 26, 2001
Received: October 29, 2001

Dear Ms. Courtney:

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.

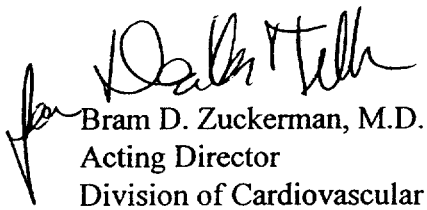
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Pump Tubing

Indications For Use:

Intended Use Described In The 510(k):

The *Pump Tubing* is intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary bypass procedures. The *tubing* is also intended to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit.

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

Garry A. Courtney 10/26/01

Garry A. Courtney
Regulatory Affairs
Olson Medical Sales, Inc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013578