DEC 10 1999

K993062

Section II

Summary of Safety And Effectiveness Information Pertaining To Substantial Equivalence

Device Common Name: Chest Drainage Tubing

Classification Name: Cardiopulmonary Bypass Pump Tubing

Intended Use:
The chest drainage tubing is intended to serve as a conduit for the flow of body fluids that are removed from the patient, via vacuum, and delivered to a reservoir during cardiopulmonary bypass procedures.

Description:
The chest drainage tube is piece of flexible polyvinylchloride tubing that is used as a conduit for body fluids suctioned from the chest cavity and moved into a reservoir following cardiopulmonary bypass procedures. The tubing is a 40 durometer tube with an inside diameter of 0.375" and an outside diameter of 0.562".

Substantial Equivalence:
The chest drainage tubing submitted in this 510(k) is substantially equivalent in intended use, design, technology/principle of operation, materials and performance to the cleared Gish Biomedical Tubing that is cleared through K870792.

Principle of Operation/Technology:
The chest drainage tubing is used as a conduit for fluids being removed from the body following bypass procedures. The fluid is moved from the body, via vacuum, into a reservoir. This is substantially equivalent to the operation of the Gish chest drainage tubing.

Design/Materials:
Differences in the polyvinylchloride materials between the chest drainage tubing indicated in this 510(k) and the cleared Gish tubing raise no new issues of safety and effectiveness.

Performance:
The performance of the chest drainage tubing presented in this 510(k) is substantially equivalent to the performance of the cleared Gish tubing.

Additional Safety Information

Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10 to the negative sixth.

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

Blood contacting materials were tested in accordance with the tests 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.

The expiration dating of the submitted components is controlled by the component with the shortest expiry that is included in a kit, or two years; whichever is the shortest duration.

Conclusion

The convenience kit component submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared device indicated within. Differences between the submitted components and the corresponding cleared devices do not raise any new issues of safety or effectiveness.

Olson Medical Sales' 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 a patent infringement action.

This Summary of Safety and Effectiveness was prepared on September 9, 1999.

This Summary was prepared by: Garry A. Courtney
Regulatory Affairs Specialist

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Olson Medical Sales, Inc
Mr. Gary A. Courtney
Regulatory Affairs
C/O Terumo Medical Corporation.
2101 Cottontail Lane
Somerset, NJ 08873

Re: K993062
Chest Drainage Tubing
Regulatory Class: II (Two)
Product Code: DWE
Dated: September 10, 1999
Received: September 13, 1999

Dear Mr. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Wolf Sapirstein MD for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Component For Cardiovascular Procedure Kit – Chest Drainage Tubing

Indications For Use:

The **Chest Drainage Tubing** is intended to serve as a conduit for the flow of body fluids that are removed from the patient, via vacuum, and delivered to a reservoir during cardiopulmonary bypass procedures.

Garry A. Courtney
Regulatory Affairs Associate
Terumo Medical Corporation

(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 Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993062

(Optional Format 1-2-96)

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