

NOV 10 1999

K992906

Section II

**Summary of Safety and Effectiveness Information  
Pertaining To Substantial Equivalence**

**Device Common Name:** Adapters

**Classification Name:** Adapter, Stopcock, Manifold, Fitting,  
Cardiopulmonary Bypass

**Intended Use:**

The adapters are intended to be used to interconnect tubing and other devices during cardiopulmonary bypass procedures.

**Device Description:**

The adapters are used in connecting oxygenators, reservoirs, filters, tubing, and other cardiopulmonary bypass components into circuits used in surgical procedures requiring extracorporeal support.

The adapters are of the following generic types: straight adapters with or without luer locking mechanisms (male and female), large bore adapters, three-way connectors, and four-way connectors.

The materials used in the manufacturing of these adapters includes polycarbonate, acrylic, and Acrylonitrile-Butadiene-Styrene (ABS).

Note: The cleared Medtronic adapters are comprised of plexiglas and polyvinylchloride.

**Substantial Equivalence:**

The adapters presented in this 510(k) are substantially equivalent in intended use, design, technology and principles of operation, materials and performance to the cleared Medtronic "Y" adapter (K790563) and the Medtronic 3/16" Large Bore Male adapter (K830728).

**Principle of Operation/Technology:**

The adapters presented in this submission perform under the same principles as the cleared Medtronic components. Each is used to interconnect cardiopulmonary bypass components to provide a pathway for blood and other extracorporeal fluids.

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**Design/Materials:**

Differences in design and materials between the adapters indicated in this submission and the cleared Medtronic adapters raise no new issues of safety and effectiveness.

**Performance:**

The performance of the adapters presented in this submission is substantially equivalent to the performance of the Medtronic adapters.

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**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 ( $\leq$  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 components submitted in this 510(k) are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared devices indicated within. Differences between the submitted adapters and the cleared adapters 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.

Section II

**Summary of Safety and Effectiveness Information  
Pertaining To Substantial Equivalence**

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

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

This Summary was prepared for: OLSON MEDICAL SALES  
28 Howe Street  
Ashland, MA 01721  
Phone: 508-881-2250  
Fax: 508-881-4858



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Olson Medical Sales, Inc.  
Mr. Garry A. Courtney  
Regulatory Affairs Association  
Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921

Re: K992906  
Components For Cardiovascular Procedure Kit  
Regulatory Class: II (TWO)  
Product Code: 74 DTL  
Dated: August 23, 1999  
Received: August 30, 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.

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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,



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: Components For Cardiovascular Procedure Kit

**Indications For Use:**

The **Adapters** are intended to be used to interconnect tubing and other devices during cardiopulmonary bypass procedures.

Garry A. Courtney  
Regulatory Affairs Associate  
Terumo Medical Corporation

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(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)

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \* 992906