K032128

Terumo AL8X Arterial Filter with X-Coating

AUG 01 2003

Submitter Information:

This submission was prepared in July 2003 by:
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125 Blue Ball Road
Elkton, MD 21921
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Device Names:

Proprietary Name:	Terumo AL8X Arterial Filter with X-Coating
Common Name:	Arterial Line Blood Filter

Device Classifications:

Device Classification Name:	Cardiopulmonary Bypass Arterial Line Blood Filter
Device Classification:	The Terumo AL8X Arterial Filter with X-Coating is classified as a Class II device per 21 CFR § 870.4260
Regulation Number:	21 CFR § 870.4260

Predicate Device:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following device:

Pall Medical AL8 Arterial Filter – (K834380).

Intended Use:

The Terumo AL8X Arterial Blood Filter for extra-corporeal service is indicated for use in all cardiopulmonary bypass procedures for the removal of micro-emboli greater than 40 microns in size, including gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris from the arterial line. The device may be used in procedures lasting up to 6 hours in duration.

Principles of Operation and Technology:
The Terumo AL8X Arterial Filter performs its functions using two basic forms of technology. As a filtration device, particulates in the blood stream are captured and removed from the blood flow as blood passes through the 40 μm filter mesh material that is contained within the device housing. The 40 μm filter mesh material establishes a physical barrier that entraps particulate matter and prevents it from moving downstream of the arterial filter assembly.

As an air-removal device, the Terumo AL8X Arterial Filter is designed so that air is removed from the blood stream as a result of centripetal force. The blood inlet port of the device is positioned on the upper-side axis of the polycarbonate housing, thereby creating a spiral blood flow pattern as blood enters the device. Because the blood flows through the device in a spiral motion, centripetal forces cause the air bubbles to migrate towards the top of the housing assembly. The top of the housing assembly has a slight conical-shape, thereby facilitating air movement towards the purge port located at the top of the assembly.

Design and Materials:
The design of the Terumo AL8X Arterial Filter is such that it will remove particulates while simultaneously facilitating the removal of air that might be in the blood flow. The blood-contacting surfaces of the device are coated with Terumo's polymer coating solution. The device accomplishes its intended use primarily due to its design characteristics.

The filter is comprised of an outer housing that contains a smaller inner housing. The outer housing is cylindrical in shape and has a slight conical-shaped lid assembly with an air vent port. The blood inlet port is positioned along the upper-side axis of the outer housing and provides the entry point for blood. The base of the housing contains the blood outlet port.

The inner housing of the device contains a screen filter through which blood will pass through for filtration of particulate matter. After the blood has been filtered, it then exits the assembly via the blood outlet port.

The materials of construction for the Terumo AL8X Arterial Filter are identical to the materials used in the predicate Pall AL8 Arterial Filter – except that the Terumo device contains a polymer coating which is not present on the predicate device. The difference in the materials do not raise any new issues of safety or effectiveness of the device, as the polymer coating has been demonstrated to be safe in many other Terumo devices that have been cleared by the United States Food and Drug Administration.

Performance Evaluations:

Terumo Cardiovascular Systems Corporation conducted several evaluations of the Terumo AL8X Arterial Filter to demonstrate its equivalence to the Pall AL8 Arterial Filter. Terumo conducted the following *in-vitro* performance tests to demonstrate equivalence:

- Filtration Efficiency
- Air Handling Capabilities
- Device Effect Upon Cellular Blood Components
- Pressure Drop
- Mechanical Integrity
- Static Priming Volume
- Evaluation of the Connection of PVC Tubing to Inlet/Outlet Ports.

Substantial Equivalence Comparison:

The Terumo AL8X Arterial Filter is substantially equivalent to the predicate Pall AL8 Arterial Filter device as follows:

- Intended Use: The intended uses of the Terumo AL8X Arterial Filter and the predicate Arterial Filter are exactly the same. Each of the Arterial Filter devices is for extra-corporeal service in all cardiopulmonary bypass procedures for the removal of micro-emboli greater than 40 microns in size, including gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris from the arterial line. The devices are also exactly the same in that each device may be used in procedures lasting up to 6 hours in duration.

  There are no differences in Intended Use between the Terumo AL8X Arterial Filter and the Pall Medical AL8 Arterial Filter.

- Principles of Operation and Technology: The operation and technology of the Terumo AL8X Arterial Filter and the predicate device are identical. The devices operate in a manner where two basic forms of technology are utilized. As filtration devices, particulates in the blood stream are captured and removed from the blood flow as blood passes through a 40 μm filter mesh material that is contained within the device housing. The 40 μm filter mesh material establishes a physical barrier that entraps particulate matter and prevents it from moving downstream of the arterial filter assembly.

  As air-removal devices, each of the filters is designed so that air is removed from the blood stream as a result of centripetal force. The blood inlet port of each device is positioned on the upper-side axis of the polycarbonate housing, thereby creating a spiral blood flow pattern as blood enters the devices. Because the blood flows through the devices in a spiral motion, centripetal forces cause the air bubbles to migrate towards the top of the housing assembly. The top of the housing assembly has a slight conical-shape, thereby facilitating air movement towards the purge port located at the top of the assembly.

  There are no differences in operation or technology between the Terumo AL8X Arterial Filter and the Pall Medical AL8 Arterial Filter.

- Design and Materials: The design and the materials of the Terumo AL8X Arterial Filter and the predicate device are essentially the same. The design of the two devices is identical in that they are each a polycarbonate housing with an inner filter – and intended to remove particulate matter and air bubbles.

  The devices are manufactured with the exact same materials. These materials include polycarbonate, polyester, polypropylene, acrylonitrile-butadiene-styrene (ABS) and polyvinyl chloride.

  The Terumo AL8X Arterial Filter contains X-Coating, which is a biocompatible surface coating that reduces platelet adhesion to the device. The use of X-Coating has

been demonstrated as safe and raises no new issues of safety and/or effectiveness. The X-Coating is not present on the predicate Pall Medical AL8 Arterial Filter.

- Performance: Comparisons of the performance of the Terumo AL8X Arterial Filter and the predicate device were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the devices.

Substantial Equivalence Summary:

In summary, the Terumo AL8X Arterial Filter and the predicate Pall AL8 Arterial Filter are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate 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}.
- Biocompatibility studies have been conducted on the materials that are used in the construction of the Terumo AL8X Arterial Filter device - as 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]. All blood-contacting materials have been found to meet the applicable biocompatibility standards.
- Terumo conducted studies for materials characterization, including physico-chemical profiles of aged and nonaged devices.
- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study (with an oxygenator device). No adverse conditions were noted.

Conclusion:

In summary, the Terumo AL8X Arterial Filter is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate Pall AL8 Arterial Filter (K834380).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Terumo Cardiovascular Systems Corporation
c/o Mr. Garry A. Courtney, MBA, RAC
Senior Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K032128
Trade Name: Terumo AL8X Arterial Filter with X-Coating
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary bypass arterial line blood filter
Regulatory Class: Class II (two)
Product Code: DTM
Dated: July 8, 2003
Received: July 10, 2003

Dear Mr. 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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: **Terumo AL8X Arterial Filter with X-Coating**

Indications For Use:

The Terumo AL8X Arterial Blood Filter for extra-corporeal service is indicated for use in all cardiopulmonary bypass procedures for the removal of micro-emboli greater than 40 microns in size, including gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris from the arterial line. The device may be used in procedures lasting up to 6 hours in duration.

Garry A. Courtney, MBA, RAC
Terumo Cardiovascular Systems

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032128