TERUMO

K083834

APR 17 2009

Submitter Information:

This submission was prepared in December 2008 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Terumo Pall AL6X Arterial Filter	Cardiopulmonary Bypass Arterial Line Blood Filter (Code: DTM)	Arterial Filter

Predicate Device(s):

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- Terumo's Capiox® AL8X Arterial Filter – K032128

Intended Use:

The Terumo Pall AL6X Arterial Filter is indicated for use in 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 and where the flow rate will not exceed 8 liters per minute.

The device may be used in procedures lasting up to 6 hours in duration.

Principles of Operation and Technology:
The Terumo Pall AL6X 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 a filter mesh material that is contained within the device housing. The filter 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 Pall AL6X 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. As 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 – where air can subsequently be purged from the circuit.

Design and Materials:
The materials that are used in the construction of the Terumo Pall AL6X Arterial Filter include polycarbonate, polyester screen, polypropylene, acrylonitrile-butadiene styrene and X-Coating™.

Performance Evaluations:
Terumo Cardiovascular Systems, in conjunction with Pall Medical Corporation, conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the AL6X Arterial Filter to the predicate AL8X Arterial Filter.

The following tests were performed, and are presented on the ensuing pages:

- Filtration Efficiency
- Air Removal Efficiency
- Hemolytic Effect Upon Cellular Components of Blood
- Pressure Drop
- Tubing Connection Strength
- Static Priming Volume
- Mechanical Integrity/Leakage Evaluation

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the Terumo Pall AL6X Arterial Filter to the predicate AL8X device, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Duration of use/6-hour use
- Product labeling
- Operation and technology of the devices
- Product design
- Materials used in device construction
- Design performance

Substantial Equivalence Statement:
The Terumo Pall AL6X Arterial Filter is substantially equivalent in intended use, duration of use, labeling, operation and technology, design, materials, and performance to the predicate Terumo AL8X Arterial Filter device.

Additional Safety Information:

- Sterilization conditions for the Terumo Pall AL6X Arterial Filter will be validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.

- The X-Coating material that is applied to the blood-contacting surfaces of the devices was evaluated in an *in-vivo* animal study conducted by Terumo Cardiovascular and Sierra Biomedical Laboratories in 1999. No adverse conditions were noted.

Conclusion:
Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Terumo Pall AL6X Arterial Filter is *substantially equivalent* to the predicate Terumo AL8X Arterial Filter device. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2009

Terumo Cardiovascular Systems Corp.
c/o Garry Courtney
125 Blue Ball Rd.
Elkton, MD 21921

Re: K083834
Terumo Pall AL6X Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Arterial Line Blood Filter
Regulatory Class: Class II (two)
Product Code: DTM
Dated: March 24, 2009
Received: March 25, 2009

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

TERUMO

SECTION 4
Indications for Use

510(k) Number (if known): Unknown at time of submission

Device Name: Terumo Pall AL6X Arterial Filter

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The device may be used in procedures lasting up to 6 hours in duration.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular Devices

510(k) Number K083834