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CAPIOX® CX*AF02X Arterial Filter with X-Coating

Submitter Information:

Name and Address:
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton MD 21921

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

Date of Preparation: May 15, 2001

Device Names:

Proprietary Name: CAPIOX® Arterial Filter with X-Coating
Product Code: CX*AF02X
Common Name: Arterial Line Blood Filter
Classification Name: Cardiopulmonary Bypass Arterial Line Blood Filter

Predicate Device:

Terumo Cardiovascular Systems Corporation has identified the uncoated CAPIOX® Arterial Filter (for pediatric use), Product Code CX*AF02, as the predicate device for the determination of substantial equivalence. The predicate device is cleared with Premarket Notification K943917.

Intended Use:

The CAPIOX® Arterial Filter with X-Coating is a pediatric filter that is intended to filtrate non-biologic particles and emboli, and to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours. The polymethoxyethylacrylate coating (PMEA) is intended to reduce the adhesion of platelets to the blood-contacting surfaces of the device.

Principles of Operation and Technology:

The CAPIOX® CX*AF02X performs its functions using two basic forms of technology. As a filtration device, non-biologic particulates in the blood stream are captured and removed from the blood flow as blood passes through the 32 μm filter mesh material that is contained within the device housing. The 32 μm filter mesh material establishes a physical barrier that entraps particulate matter.

As an air-removal device, the CAPIOX® CX*AF02X 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 side axis of the hardshell 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 is conical-shaped, thereby facilitating air movement towards the air vent port that is located at the top of the assembly.

Design and Materials:
The design of the CAPIOX® CX*AF02X is such that the device meets its stated intended uses, and provides an acceptable level of performance and safety to the patient.

The device is a hardshell housing that contains a blood filter, and has both a blood inlet port and a blood outlet port. The blood inlet port is positioned along the side axis of the outer housing and provides the entry point for blood. The blood outlet port is positioned at the base of the device. The top surface of the device has a luered connection port (Air Vent Port) that will accommodate a stopcock assembly to facilitate the air removal process.

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

The materials of construction for the CAPIOX® CX*AF02X are the exact same materials that are used in the predicate uncoated CAPIOX® Arterial Filter – except for the addition of X-coating to the subject device. The differences in the materials do not raise any new issues of safety or effectiveness of the device.

Performance:
Terumo Cardiovascular Systems Corporation conducted performance evaluations of the CAPIOX® CX*AF02X to demonstrate its equivalence to the uncoated CAPIOX® Arterial Filter. The following performance tests were conducted:

- Filtration Efficiency
- Air Handling Capabilities
- Device Effect Upon Cellular Blood Components (cellular destruction)
- Pressure Drop (Short-term and 6-Hour)
- Mechanical Integrity
- Static Priming Volume
- Evaluation of the Connection of PVC Tubing to Inlet and Outlet Ports.

Substantial Equivalence Comparison:
The CAPIOX® CX*AF02X Arterial Filter with X-Coating is substantially equivalent to the uncoated CAPIOX® Arterial Filter:

- Intended Use: Both the CAPIOX® Arterial Filter with X-Coating and the predicate CAPIOX® Arterial Filter are pediatric filters that are intended to filtrate non-biologic particulates and emboli and to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours.

- Principles of Operation and Technology: The CAPIOX® CX*AF02X and the predicate arterial filter each utilize the same technologies in the operation of the devices. Air removal is accomplished through spiral blood flow patterns that create centripetal force, thereby facilitating air movement towards the air vent port. Filtration is accomplished with a polyester screen material.

  Design and Materials: The CAPIOX® CX*AF02X and the predicate arterial filter each have the same identical design in that they are each comprised of a screen mesh that is contained within a hardshell housing assembly. The screen is responsible for the removal of particulate matter while a spiral blood flow pattern facilitates air removal. Each device has a blood inlet port that provides for blood entry and a blood outlet port that provides for blood exit from the device. Each device contains a standard luer port for the attachment of a stopcock assembly to assist in air removal. The materials used in the construction of the two devices are equivalent, except that the proposed device contains X-Coating. The difference in the materials (i.e., use of X-Coating) does not create any new issues of safety or effectiveness.

- Performance: Comparisons between the performance of the CAPIOX® CX*AF02X and the predicate arterial filter were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the two devices.

Substantial Equivalence Summary:
In summary, the CAPIOX® Arterial Filter with X-Coating and the uncoated CAPIOX® Arterial Filter 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).

- Terumo Cardiovascular Systems Corporation 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 CAPIOX® Arterial Filter with X-Coating is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated CAPIOX® Arterial Filter (K943917).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2001

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

Re: K011804/S1
Trade Name: CAPIOX® Arterial Filter with X-Coating (CX*AF02X)
Regulation Number: 870.4260
Regulatory Class: II (Two)
Product Code: DTM
Dated: June 21, 2001
Received: July 2, 2001

Dear Mr. Courtney:

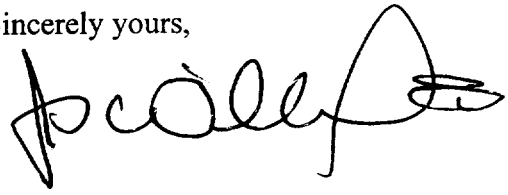
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011804

Device Name: **CAPIOX® Arterial Filter with X-Coating (CX*AF02X)**

Indications For Use:

The CAPIOX® Arterial Filter with X-Coating is a pediatric filter that is intended to filtrate non-biologic particles and emboli, and to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours. The polymethoxyethylacrylate coating (PMEA) is intended to reduce the adhesion of platelets to the blood-contacting surfaces of the device.

Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011804

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)