SEP 1 2 2005

K052205

Capiox® AF125X Arterial Filter

Device Name:

Proprietary Name:	Capiox® AF125X Arterial Filter
Common Name:	CPB Arterial Line Blood Filter

Device Classifications:

Device Classification Name:	Cardiopulmonary Bypass Arterial Line Blood Filter
Device Classification:	The Terumo AF125 Arterial Filter is classified as a Class II device per 21 CFR § 870.4260
Regulation Number:	21 CFR § 870.4260

Device Product Code(s):
The Capiox® AF125X Arterial Filter is identified by Terumo Cardiovascular Systems as product code **CX*AF125X**.

The FDA product code for Arterial Line Blood Filters is **DTM**.

Review Panel: Cardiovascular (74)

Device Intended Use:
The Capiox® AF125X Arterial Blood Filter 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.

Reason For Premarket Notification:
The Capiox® AF125X Arterial Filter is submitted as required by the United States Food and Drug Administration when marketing a new product. The Capiox® AF125X Arterial Filter is a new product – and does not necessarily reflect any modification of any existing, legally marketable products offered by Terumo.

Statement of Equivalence to Predicate Device:
The device submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the Capiox® AF200X Arterial Filter that is marketed under Premarket Notification K002026, which was cleared by FDA on September 6, 2000.

A comparison of the similarities and differences is presented in this submission. The differences between the submitted device and the predicate devices do not raise new issues of safety and effectiveness.

Section 514, Special Controls:
To the best of our knowledge, no performance standards have been established for Arterial Line Blood Filters. The following guidance document and FDA Memorandum were referenced, in part or in whole, in the preparation of this submission:

- *Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions.* FDA Document Release Date: February 21, 2000
- FDA Blue Book Memorandum G95-1 (Biocompatibility Evaluations)

Establishment Registrations:

Contact Person:	Garry A. Courtney, MBA, RAC Terumo Cardiovascular Systems Corp. 125 Blue Ball Road Elkton, MD 21921 Registration No. 1124841 Phone: 1-800-283-7866, Extension 7420 Fax: (410) 398-6079
Manufacturer/Sterilizer:	Ashitaka Factory of Terumo Corporation 150 Maimaigi-cho Fujinomiya city, Shizuoka Pref. Japan 418-0015 Registration No. 9681834
Owner Operator:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo Japan 151-0072 Registration No. 8010026
Distributor (in U.S.):	Terumo Medical Corporation 2101 Cottontail Lane Somerset, NJ 08873 Registration No. 2243441

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2005

Mr. Garry A. Courtney, MBA, RAC
Sr. Regulatory Affairs Specialist
Terumo Cardiovascular Systems Corp.
125 Blue Ball Road
Elkton, MD 21921

Re: K052205
Trade/Device Name: CAPIOX® AF125X Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: II
Product Code: DTM
Dated: August 1, 2005
Received: August 12, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

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

Enclosure

Indications for Use

510(k) Number (if known): Unkown at time of Submission K052205

Device Name: CAPIOX® AF125X Arterial Filter

Indications For Use:

The Capiox® AF125X Arterial Blood Filter 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.

8/01/2005
Garry A. Courtney, MBA, RAC
Terumo Cardiovascular Systems

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)

Donna R. Vodnes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052205