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SECTION 5 – 510(k) Summary
CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter/Reservoir

TERUMO

Submitter Information:

This submission was prepared in March 2014 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
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Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
CAPIOX®FX15 and FX25 Hollow Fiber Oxygenator/Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Arterial Filter (Code: DTM)	Arterial Filter
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir

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 devices:

- Terumo® CAPIOX® FX15 and FX25 Oxygenator/Reservoir – K071494
- Terumo® CAPIOX® FX15 and FX25 Oxygenator/Reservoir – K130520
- Terumo® CAPIOX® RX15 and RX25 Oxygenator/Reservoir – K130333

Intended Use:
The Capiox FX Hollow Fiber Oxygenator and Arterial Filter is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 3-liter and 4-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post Operative Chest Drainage Procedures.

The Capiox FX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min. when used with a 3 Liter Reservoir.

The Capiox FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

The Capiox FX Oxygenator/Reservoir/Arterial Filter assemblies can be used in procedures lasting up to 6 hours.

Principles of Operation and Technology:
The CAPIOX®FX15 and FX25 Oxygenator utilizes porous fiber technology to facilitate the transfer of gases between a blood-phase environment and a gas-phase environment for the intent of satisfying the gas exchange needs of a patient during cardiopulmonary bypass surgery. A fiber bundle offers the porous membrane surface to sufficiently permit the movement of gases through the walls of the hollow fibers via diffusion.

The CAPIOX®FX15 and FX25 device has an integrated heat exchanger that is comprised of stainless steel encased in a polycarbonate housing. The stainless steel acts as a heat transfer material that permits heat that is generated from a temperature controlled external water bath to transverse across the walls of the stainless steel to effect the necessary temperature change upon circulating blood.

With respect to the filtration of arterial blood, the Capiox® FX15 and FX25 Oxygenator/Reservoir relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

Device Description:
The CAPIOX® FX15 and FX25 Hollow Fiber Oxygenator/Arterial Filter/Reservoir contains an integrated heat exchanger system and an integrated Arterial Filter. The device may also be used in conjunction with an optional hardshell reservoir. The design provides an integrated system for ease of use – as well as independent use of the oxygenator and the hardshell reservoir when desired by the user (perfusionist).

The CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter/Reservoir device is a membrane-type oxygenator that consists of micro-porous hollow polypropylene fibers. When in use, blood flows around the outside of fibers while gas flows through the inside of the fibers. As the fibers are micro-porous, gas exchange can occur through the fiber walls by way of diffusion. The FX Oxygenator module is comprised of a *wound fiber* design whereby continuous strands of fiber are wound around a core support structure. The total amount of fiber that is exposed to blood and gas is approximately 1.5 m^2 for the FX15 and 2.5 m^2 for the FX25 model.

The screen mesh material that comprises the Arterial Filter is made of polyethylene terephthalate (PET) –and is wrapped around the outside of the hollow fiber membrane. This 32 micron mesh is responsible for the filtration of particulates from the blood stream, and also facilitates air removal from the blood.

The integrated heat exchanger contains a stainless steel bellows that facilitates the transfer of heat. The heat exchanger has a water inlet port and a water outlet port to allow water (from an external water bath) to enter and flow to the inside of steel bellows to effectively control the temperature of the blood that flows on the outside of the steel bellows.

The CAPIOX® FX15 Oxygenator may be used with a 3-liter or 4-liter hardshell blood reservoir. The CAPIOX® FX25 Oxygenator may be used with a 4-liter hardshell reservoir. The hardshell reservoir includes a positive pressure relief valve that is incorporated into the lid of the reservoir. The relief valve permits the release of positive pressure within the reservoir.

Design and Materials:
With respect to the design of the oxygenator, the design of the Terumo Cardiovascular Systems Corporation CAPIOX®FX15 and FX25 oxygenator device is identical to the predicate, Terumo Corporation CAPIOX®FX15 and FX25 oxygenator device.

With respect to the design of the Arterial Filter, the filter contained within the Terumo Cardiovascular Systems Corporation oxygenator module is identical to the predicate, Terumo Corporation CAPIOX® FX15 and FX25 oxygenator device.

With respect to the design of the Hardshell Reservoir, the Terumo Cardiovascular Systems Corporation reservoir is identical to the design of the Terumo Cardiovascular Systems Corporation reservoir that was cleared by FDA with K130333.

The materials that are used in the construction of the CAPIOX® FX15 and FX25 Oxygenator/Reservoir, but are not limited to, nylon, polycarbonate, stainless steel, polyvinyl

chloride, polyurethane, polyester, polypropylene, polyethylene terephthalate, polyethylene and X-Coating™.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter (w/Heat Exchanger) Gas Transfer Performance
- CAPIOX® FX15 and FX25 Oxygenator /Arterial Filter (w/Heat Exchanger) Pressure Drop Testing
- CAPIOX® FX15 and FX25 Oxygenator/Arterial (w/Heat Exchanger) Air Handling Performance
- CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter (w/Heat Exchanger) Testing Summary Report

The following performance testing evaluated under K071494. This new subject FX15 and FX25 oxygenator/arterial filter devices are identical to the oxygenator/arterial filter devices in K071494. The reports are included in this submission as supporting data.

- CAPIOX® FX15 Oxygenator/Arterial Filter Hemolysis Evaluation – The Effects Upon Cellular Blood Components
- CAPIOX® FX15 Mechanical/Structural Integrity Oxygenator/Arterial Filter
- CAPIOX® FX15 Oxygenator/Arterial Filter Priming Volume- Evaluation of Priming Volume
- CAPIOX® FX15 Oxygenator/Arterial Filter (w/Heat Exchanger) – Heat Exchanger Performance Factor
- CAPIOX® FX15 Oxygenator/Arterial Filter – Tubing Connection Strength
- CAPIOX® FX15 Oxygenator/Arterial Filter – Filtration Efficiency
- CAPIOX® FX25 Oxygenator/Arterial Filter Hemolysis Evaluation – The Effects Upon Cellular Blood Components
- CAPIOX® FX25 Mechanical/Structural Integrity Oxygenator/Arterial Filter
- CAPIOX® FX25 Oxygenator/Arterial Filter Priming Volume- Evaluation of Priming Volume
- CAPIOX® FX25 Oxygenator/Arterial Filter (w/Heat Exchanger) – Heat Exchanger Performance Factor
- CAPIOX® FX25 Oxygenator/Arterial Filter – Tubing Connection Strength
- CAPIOX® FX25 Oxygenator/Arterial Filter – Filtration Efficiency

Substantial Equivalence Comparison:
The information presented in this section depicts a comparison between the subject of this 510(k) submission, the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter/Reservoir, and the predicate, Terumo Corporation CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter/Reservoir. The Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter is identical to the predicate,

K071494, Terumo Corporation CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter, as Terumo Corporation will be providing the oxygenator/arterial filter assembly to Terumo Cardiovascular Systems Corporation to assemble with the reservoir and sterilize. The reservoir used with the Terumo Cardiovascular Systems Corporation Capiox® FX15 and FX25 Oxygenator/Reservoir is the identical reservoir that was cleared under K130333.

- ***Comparison of Intended Use:***
  The Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 devices and the predicate, Terumo Corporation Capiox® FX15 and FX25 devices are exact in their intended uses:

  The CAPIOX® FX Hollow Fiber Oxygenator and Arterial Filter is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

  The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

  The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

  The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 3-liter and 4-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post Operative Chest Drainage Procedures.

  The CAPIOX® FX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min. when used with a 3 Liter Reservoir.

  The CAPIOX® FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

  The CAPIOX® FX Oxygenator/Reservoir/Arterial Filter assemblies can be used in procedures lasting up to 6 hours.

- ***Duration of Use:***
  The Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 devices and the predicate, Terumo Corporation Capiox® FX15 and FX25 devices can both be used in procedures lasting up to 6 hours.

- ***Comparison of Labeling:***
  Both the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 devices and the predicate, Terumo Corporation CAPIOX® FX15 and FX25 devices are offered with

adequate Instructions for Use and other product labeling as required by regulation. The Instructions for Use for the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 device are presented in the Appendices of this submission; the Instructions for Use for the predicate, Terumo Corporation CAPIOX® devices are also presented in the Appendices of this submission.

- ***Comparison of Principles of Operation & Technology:***
  Both the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 Hollow Fiber Oxygenator and the predicate K071494 CAPIOX® FX15 and FX25 devices utilize the exact same technologies and principles of operation. The reservoir used in the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 Oxygenator/Reservoir is the identical reservoir that was cleared under K130333.

  The predicate CAPIOX® FX15 and FX25 and the predicate devices are substantially equivalent with respect to operation and technology.

- ***Comparison of Design:***
  With respect to the design of the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 device, the oxygenator/arterial filter is identical to the predicate K071494 Terumo Corporation CAPIOX® FX15 and FX25 oxygenator/arterial filter, and the reservoir is identical to the Terumo Cardiovascular Systems Corporation reservoir cleared under K130333.

- ***Comparison of Materials:***
  With respect to materials of construction, the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 oxygenator/arterial filter are identical to the predicate, Terumo Corporation CAPIOX® FX15 and FX25 oxygenator/filter. The materials in the Terumo Cardiovascular Systems Corporation reservoir are identical to the predicate device, Terumo Cardiovascular Systems Corporation reservoir cleared under K130333.

- ***Comparison of Performance:***
  The Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 device exhibits equivalent performance to the predicate, Terumo Corporation Capiox® FX15 and FX25 predicate device – as there have been no changes made to the finished device that would alter the performance of the device.

Substantial Equivalence Statement:
The Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 devices and the predicate, Terumo Corporation, CAPIOX® FX15 and FX25 devices 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 to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed the maximum residue limits at the time of product distribution.

- Terumo maintains biocompatibility studies 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]. The blood contacting materials were found to be biocompatible.

Conclusion:

In summary, Terumo deems the Terumo Cardiovascular Systems Corporation CAPIOX® FX15 and FX25 device is substantially equivalent to the predicate, Terumo Corporation, CAPIOX® FX15 and FX25 device with respect to intended use, duration of use, design, materials, principles of operation, performance, and specifications. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 2, 2014

Terumo Cardiovascular Systems Corporation
Eileen Dorsey
Regulatory Affairs Manager
125 Blue Ball Road
Elkton, MD 21921

Re: K140774
Trade/Device Name: CAPIOX® FX15 and FX25 Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTM, DTN
Dated: March 27, 2014
Received: March 28, 2014

Dear Ms. Dorsey:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

CAPIOX® FX15 and FX25 Oxygenator/Arterial Filter/Reservoir

510(k) Number (if known): K140774 Unknown at time of Submission

Device Name: **CAPIOX® FX15 and FX25 Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Reservoir**

Indications For Use:

The Capiox FX Hollow Fiber Oxygenator and Arterial Filter is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 3-liter and 4-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post Operative Chest Drainage Procedures.

The Capiox FX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min. when used with a 3 Liter Reservoir.

The Capiox FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

The Capiox FX Oxygenator/Reservoir/Arterial Filter assemblies can be used in procedures lasting up to 6 hours.

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)