



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

November 19, 2015

Terumo Cardiovascular Systems Corporation
Jaime Lee
Regulatory Affairs Associate
125 Blue Ball Road
Elkton, Maryland 21921

Re: K151791

Trade/Device Name: Terumo Capiox FX15 Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir, Terumo Capiox FX25 Advance 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, DTN, DTR, DTM

Dated: October 21, 2015

Received: October 22, 2015

Dear Jaime Lee:

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" (21 CFR 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



SECTION 4 – Indications for Use
Capiox® FX15 and FX25 Advance Oxygenators with Integrated Arterial Filter
and 4-Liter Hardshell Reservoir

510(k) Number (if known): K151791

Device Name: CAPIOX® FX15 and FX25 Advance Oxygenators with Integrated Arterial Filter and Hardshell Reservoir

Indications for Use:

The Capiox® FX Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir 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 Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir (both 3-liter and 4-liter) is for use with patients when the required blood flow rate will not exceed 5.0 L/min. The Capiox® FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

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

NOTE: The indication change that increases the maximum flow rate of the FX15 with the 3-Liter reservoir from 4.0 liters per minute to 5.0 liters per minute has been submitted as a part of Traditional 510(k) application K151389. This Special 510(k) application is solely intended for the FX15 and FX25 oxygenator used with the 4-Liter reservoir. There is no indication change with respect to the 4-Liter reservoir.

Prescription Use XX OROver-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (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)

Submitter Information

This submission was prepared in June 2015 by:

Jaime Lee
 Regulatory Affairs Associate
 Terumo Cardiovascular Systems Corporation
 125 Blue Ball Road
 Elkton, MD 21921
 Telephone: 1-800-262-3304, Ext. 7650
 Fax: 410-392-7171

This submission was prepared for:

Terumo Cardiovascular Systems Corporation
 125 Blue Ball Road
 Elkton, MD 21921
 Facility Registration No. 1124841

Device Names/Classifications

<u>Proprietary Name</u>	<u>Classification Name</u>	<u>Common Name</u>
Capiox® FX15 and FX25 Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Arterial Line Blood Filter (Code: DTM)	Arterial Filter

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® FX Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Reservoir – K140774.

Intended Use

The Capiox® FX Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir 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 Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir (both 3-liter and 4-liter) is for use with patients when the required blood flow rate will not exceed 5.0 L/min. The Capiox® FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

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

NOTE: The indication change that increases the maximum flow rate of the FX15 with the 3-Liter reservoir from 4.0 liters per minute to 5.0 liters per minute has been submitted as a part of Traditional 510(k) application K151389. This Special 510(k) application is solely intended for the FX15 and FX25 oxygenator used with the 4-Liter reservoir. There is no indication change with respect to the 4-Liter reservoir.

Principles of Operation and Technology

The modified Capiox® FX15 and FX25 Advance Oxygenators (with 4-liter Reservoir) utilize 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 modified Capiox® FX15 and FX25 Advance devices have 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 modified Capiox® FX15 and FX25 Advance Oxygenators rely upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

Design and Materials

The design of the subject and predicate devices is nearly identical. No modifications are being made to the oxygenator or arterial filter components of the device. The reservoir component of the devices remain identical to the design of the original reservoir that was cleared by FDA with K140774, except for the following:

- The geometry of the polycarbonate Venous Inlet Port is being modified from an angled design to a curved design. The curved design for the inlet port will facilitate enhanced air handling within the device.
- The venous port drop tube within the reservoir is being modified from a straight design at the lower end of the tube to a flared design, which is intended to improve flow dynamics through the reservoir.
- The polyvinyl chloride flexible tubing used in the Reservoir is being changed from PVC tubing with DEHP plasticizer to PVC tubing with TOTM plasticizer. This change will address growing market concerns with the use of DEHP and to meet pending regulatory

requirements in the global market. The modified tubing affects the venous drop tubes, the sampling manifold tubing, the arterial quick disconnect and the arterial purge line tubing.

- The minimum operating level of the Reservoir will be reduced from 200mL to 150mL.
- The decal-type graduate scale label affixed to the outside surface of the Reservoir is being increased in length to offer convenience to the user-perfusionist.

The materials that are used in the construction of the Capiox® FX15 and FX25 Advance Oxygenators include 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. For this submission, Terumo Cardiovascular has completed the following (simulated use) performance evaluations on the reservoir:

- Verification Testing of Curved Inlet Reservoir Connections
- Verification Testing of Pressure Drop
- Verification Testing of Hemolysis
- Verification Testing of Reservoir Venous Filter Defoaming
- Verification Testing of Clotting Performance
- Verification Testing of Air Handling Performance
- Flow Dynamics Evaluation of Curved Inlet Port
- Aged Mechanical Integrity Testing

Note: For this submission, it is not necessary to conduct performance testing on the oxygenator/arterial filter module since there have been no changes to the oxygenator/arterial filter. The performance of the oxygenator/arterial filter module is completely independent of the reservoir. Changes made to the reservoir have no impact whatsoever on the performance of the oxygenator.

Substantial Equivalence Comparison

The information presented in this section depicts a comparison between the subject Capiox® FX15 and FX25 Advance devices and the predicate Terumo Cardiovascular Systems Capiox® FX15 and FX25 Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Reservoir (K140774).

- ***Comparison of Intended Use***

The subject Capiox® FX15 and FX25 Advance devices with the 4-liter Reservoir and the predicate Capiox® FX15 and FX25 devices with a 4-liter Reservoir are identical.

NOTE: The use of the FX15 with the 3-Liter reservoir has been submitted as a part of Traditional 510(k) application K151389. This Special 510(k) application is solely intended for the FX15 and FX25 oxygenator used with the 4-Liter reservoir.

- ***Duration of Use***

The subject Capiox® FX15 and FX25 Advance devices and the predicate devices can be used in procedures lasting up to 6 hours.

- ***Comparison of Labeling***

The subject Capiox® FX15 and FX25 Advance devices and the predicate Capiox® FX15 and FX25 devices are offered with adequate Instructions for Use and other product

labeling as required by regulation. The product IFUs are equivalent and differ only indicating a higher maximum flow rate for the FX15 devices when used with a 3-Liter reservoir – and in some product illustrations.

NOTE: The indication change that increases the maximum flow rate of the FX15 with the 3-Liter reservoir from 4.0 liters per minute to 5.0 liters per minute has been submitted as a part of Traditional 510(k) application K151389. This Special 510(k) application is solely intended for the FX15 and FX25 oxygenator used with the 4-Liter reservoir. There is no indication change with respect to the 4-Liter reservoir.

- ***Comparison of Principles of Operation & Technology***

Both the subject Capiox[®] FX15 and FX25 Advance Oxygenators and the predicate Capiox[®] FX15 and FX25 devices utilize the exact same technologies and principles of operation. There are absolutely no differences between the subject and predicate devices with respect to product technology or product operation.

- ***Comparison of Design***

The design of the subject Capiox[®] FX15 and FX25 Advance Oxygenators are equivalent to the design of the predicate Capiox[®] FX15 and FX25 devices, except for the following:

- The geometry of the polycarbonate Venous Inlet Port is being modified from an angled design to a curved design. The curved design for the inlet port will facilitate enhanced air handling within the device.
- The venous port drop tube within the reservoir is being modified from a straight design at the lower end of the tube to a flared design, which is intended to improve flow dynamics through the reservoir.

Performance evaluations have demonstrated substantial equivalence across varying elements of design.

- ***Comparison of Materials***

The materials of construction between the subject Capiox[®] FX15 and FX25 Advance Oxygenators and the predicate Capiox[®] FX15 and FX25 devices are identical with the exception of the plasticizer that is used in the polyvinyl chloride tubing (drop tubes, sampling manifold, purge lines). The subject devices include PVC tubing with TOTM plasticizer while the predicate devices include PVC tubing with DEHP as the plasticizer. Performance evaluations have demonstrated substantial equivalence between the two materials.

- ***Comparison of Performance***

The subject Capiox[®] FX15 and FX25 Advance devices exhibit equivalent performance to the predicate devices. A series of simulated use testing of the reservoirs demonstrates substantial equivalence between the two designs.

Substantial Equivalence Statement

The Terumo Cardiovascular Systems Corporation Capiox[®] FX15 and FX25 Advance devices (with 4-liter Reservoir) and the predicate Capiox[®] FX15 and FX25 devices (with 4-liter Reservoir) are substantially equivalent in intended use, principles of operation and technology, design, materials, and performance. The noted differences between the subject devices 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, the Terumo Cardiovascular Systems Corporation Capiox[®] FX15 and FX25 Advance devices with 4-liter Reservoir are substantially equivalent to the predicate (K140774) Capiox[®] FX15 and FX25 devices with 4-liter Reservoir with respect to intended use, principles of operation and technology, design, materials, performance, and specifications. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.