



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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October 20, 2015

Terumo Cardiovascular Systems Corporation  
Garry Courtney  
Regulatory Affairs, Sr. Manager  
125 Blue Ball Road  
Elkton, Maryland 21921

Re: K151389

Trade/Device Name: Terumo Capiox FX15 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, DTM, DTR  
Dated: September 4, 2015  
Received: September 8, 2015

Dear Garry 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. 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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman", is written over a faint, semi-transparent watermark of the FDA logo.

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

Enclosure



Section 3 - Indications for Use  
Capiox® FX Advance Oxygenator  
with Integrated Arterial Filter and Hardshell Reservoir

510(k) Number (if known): K151389

Device Name: Capiox® FX Advance Oxygenator 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 Advance 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.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**Section 4 - 510(k) Summary**  
**Capiox® FX Advance Oxygenator**  
**with Integrated Arterial Filter and Hardshell Reservoir**

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***Submitter Information:***

This submission was prepared in May 2015:

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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® FX Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Cardiopulmonary Bypass Arterial Filter (Code: DTM)	Arterial Filter
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger

***Predicate Device:***

The device submitted in this 510(k) features characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following predicate device(s):

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

***Intended Use:***

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

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

***Principles of Operation and Technology:***

The Capiox<sup>®</sup> FX15 Advance Oxygenators 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 provides a porous membrane surface to sufficiently permit the movement of gases through the walls of the hollow fibers via diffusion.

The Capiox<sup>®</sup> FX15 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 Capiox<sup>®</sup> FX15 Advance devices rely 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<sup>®</sup> FX15 Advance devices each contain an integrated heat exchanger system and an integrated arterial filter, and a detachable hardshell reservoir. The oxygenator/arterial filter module can be used independent of the hardshell reservoir since the performance of the oxygenator/arterial filter is not dependent upon the use of a Terumo reservoir. The design provides an integrated system for ease of use and offers options to the user-perfusionist.

The Capiox<sup>®</sup> FX15 Advance devices are membrane-type oxygenators 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. Because the fibers are micro-porous, gas exchange can occur through the fiber walls by way of diffusion. The Capiox<sup>®</sup> FX15 Advance 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<sup>2</sup> for the FX15 models.

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<sup>®</sup> FX15 Advance Oxygenator may be used with a 3-liter or 4-liter hardshell blood reservoir. The 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:***

The design of the subject and predicate devices is nearly identical. The only design difference is that the modified device features a curved inlet port verses an angled inlet port with the predicate, and, the subject device features flared inlet port drop tubes verses straight inlet drop tubes with the predicate device. The materials that are used in the construction of the Capiox<sup>®</sup> Advance devices include, nylon, polycarbonate, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene terephthalate, polyethylene and X-Coating<sup>™</sup>.

***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
- Air Handling (Worst Case challenge - with 4 Liter Reservoir at hi flow rate)
- Flow Dynamics of Curved Inlet Port

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 module. 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 Advance devices and the predicate Terumo Cardiovascular Systems Capiox® FX15 Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Reservoir (K140774).

- ***Comparison of Intended Use:***

The product Intended Use statement between the subject Capiox® Advance and the predicate devices is nearly identical. The only difference that exists between the two devices is that the subject Capiox® Advance device permits a maximum flow rate of 5.0 liters per minutes when used with the 3-liter reservoir. The predicate device indicates a maximum flow rate of 4.0 liters per minute when used with the 3-liter reservoir.

- ***Duration of Use:***

The subject Capiox® Advance devices and the predicate devices are each indicated for use in procedures lasting up to 6 hours.

- ***Comparison of Labeling:***

Both the subject Capiox® Advance devices and the predicate devices are offered with adequate Instructions for Use and other product labeling as required by regulation. The product IFU's are equivalent, and differ only in indicating a higher maximum flow rate for the FX15 devices when used with a 3 liter reservoir – and in some product illustrations.

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

Both the subject Capiox® Advance devices and the predicate Capiox® FX15 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 Advance devices are equivalent to the design of the predicate Capiox® devices. The only differences that exists are:

- the use of a curved venous inlet port at the top of the reservoir for the Advance device verses an angled inlet port for the predicate device
- flaring of the venous inlet drop tubes in the reservoir

Performance evaluations have demonstrated equivalence between the varying designs.

- ***Comparison of Materials:***

The materials of construction between the subject Capiox® FX15 Advance devices and the predicate 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 as a plasticizer while the predicate device includes PVC tubing with DEHP as the plasticizer. Performance evaluations have demonstrated equivalence between the two materials.

- ***Comparison of Performance:***

The subject Capiox® FX15 Advance devices exhibit equivalent performance to the predicate devices. Through a series of simulated-use testing of the reservoirs, equivalence between the two designs was demonstrated.

***Substantial Equivalence Statement:***

The Terumo Cardiovascular Systems Corporation Capiox® FX15 Advance devices and the predicate Capiox® FX15 devices are substantially equivalent in intended use, principles of operation and technology, design and 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 ( $\leq 24$  hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

***Conclusion:***

In summary, Terumo deems the Terumo Cardiovascular Systems Corporation Capiox® FX15 Advance devices are substantially equivalent to the predicate (K140774), Capiox® FX15 devices 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.