



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

December 02, 2015

Terumo Cardiovascular Systems Corp.  
Joshua Ewing  
Senior Regulatory Affairs Associate  
125 Blue Ball Road  
Elkton, Maryland 21921

Re: K153140

Trade/Device Name: Capiox SX18 Hollow Fiber Oxygenator with detachable Hardshell Reservoir,  
Capiox SX25 Hollow Fiber Oxygenator with detachable Hardshell Reservoir,  
X-Coated Capiox SX18 Hollow Fiber Oxygenator with/without detachable Hardshell Reservoir,  
X-Coated Capiox SX25 Hollow Fiber Oxygenator with/without detachable Hardshell Reservoir

Regulation Number: 21 CFR 870.4350

Regulation Name: Cardiopulmonary Bypass Oxygenator

Regulatory Class: Class II

Product Codes: DTZ, DTN, DTR, DTP

Dated: October 28, 2015

Received: October 30, 2015

Dear Joshua Ewing:

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



**Submitter Information:**

## Primary Contact:

This submission was prepared in October 2015 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation  
 125 Blue Ball Road  
 Elkton, MD 21921  
 Registration #1124841

**Device Names/Classifications:**

<u>Proprietary Name</u>	<u>Classification Name</u>	<u>Common Name</u>
Capiox® SX18/25 Hollow Fiber Oxygenator with detachable Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Defoamer (Code: DTP)	Defoamer
X-Coated Capiox® SX18/25 Hollow Fiber Oxygenator with detachable Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Defoamer (Code: DTP)	Defoamer

***Predicate Device(s):***

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- CAPIOX SX18 and SX25 Hollow Fiber Oxygenators (with/without X-Coating), with/without Detachable Reservoirs (K130359)

***Indications for Use:***

**The intended use remains the same as the intended use in the cleared submission (K130359). There have been no changes to the indications or intended use of the modified devices as a result of the modifications to the hardshell reservoir. There are no modifications to the SX oxygenator.**

The (X-Coated) Capiiox® SX25 and SX18 Hollow Fiber Oxygenators with/without Detachable Hardshell Reservoirs are used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery for periods up to 6 hours.

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

The (detachable) hardshell reservoir is used to store blood during extracorporeal circulation from both 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 Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

(The X-Coating™ is a polymer coating that is applied to blood contacting surfaces of the oxygenator to reduce the adhesion of platelets to the surfaces of the device.)

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

**The technological characteristics and principles of operation remain the same as that of the predicate devices previously cleared (K130359) for all devices in this submission. There have been no changes to the fundamental scientific technology of the modified devices.**

The modified and predicate Capiiox® SX18/25 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 modified and predicate Capiox® SX18/25 Oxygenator 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 blood, the modified and predicate Capiox® Hardshell Reservoir relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

***Design and Materials:***

With respect to the design of the oxygenator, the design of the Capiox® SX18/25 oxygenator device is unaffected by the changes being incorporated at this time. The subject of this Special 510(k) is a modification being made to the Hardshell Reservoir.

With respect to the design of the Hardshell Reservoir, the reservoir component remains identical to the design of the original reservoir that was cleared by FDA with (K130359) – except the modified device will include PVC tubing (with TOTM plasticizer) for a flared venous inlet drop tube, auxiliary tube, sampling manifold tubing, and purge line tubing. There are no other modifications being made to the device.

The materials that are used in the construction of the CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir may include, but are not limited to, nylon, polycarbonate, stainless steel, polyvinyl chloride (TOTM plasticizer and DEHP plasticizer), polyurethane, polyester, polypropylene, polyethylene, and X-Coating™.

Device Characteristics	Modified Device	Predicate Device
Venous Inlet Drop Tube	Flared, TOTM plasticizer	Non-Flared, DEHP plasticizer
Auxiliary Drop Tube	Straight, TOTM plasticizer	Straight, DEHP plasticizer
Sampling Manifold Tubing	TOTM plasticizer	DEHP plasticizer
Purge line Tubing	TOTM plasticizer	DEHP plasticizer

The flared venous drop tube will improve flow dynamics within the reservoir. The use of a TOTM plasticizer instead of a DEHP plasticizer allows Terumo to adjust to pending regulatory requirements. No modifications are being made to the oxygenator. No additional modifications, other than what is listed above, are being made to the hardshell reservoir.

Terumo Cardiovascular Systems Corporation concludes that the differences between the modified device and the predicate device do not affect the intended use of the device nor do they affect safety and effectiveness of the device when used as labeled.

***Performance Evaluations:***

Terumo Cardiovascular Systems Corporation conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the subject device to the predicate device:

- Hemolysis Testing
- Air Handling
- Reservoir Pressure Drop
- Venous Defoaming

***Substantial Equivalence Comparison:***

In demonstrating substantial equivalence of the *modified* CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir to the predicate CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Target Population
- Duration of use
- Product design
- Materials used in device construction
- Principles of Operation and Technology
- Device Performance
- Product labeling

***Substantial Equivalence Statement:***

The modified CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir and the predicate CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir 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 for CAPIOX® SX18/25 Oxygenator/Hardshell Reservoirs are validated to meet the requirements established in EN ISO 11135-1:2007. The validated processes ensure a minimum Sterility Assurance Level of 10<sup>-6</sup>. Product sterilization is controlled through strict maintenance of the processing parameters and, in some cases, post-sterilization biological indicator testing (if required for routine processing). Post-sterilization release for use is determined with consideration to maximum. Ethylene Oxide and Ethylene Chlorhydrin residue limits and maximum levels of exposure in accord with ANSI/AAMI/ISO 10993-7.

***Conclusion:***

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems Corporation concludes that the *modified* CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir is *substantially equivalent* to the predicate *modified* CAPIOX® SX18/25 Oxygenator/Hardshell Reservoir. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.