



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

December 03, 2015

Terumo Cardiovascular Systems Corporation
Tierra Brown
Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, Maryland 21921

Re: K153213

Trade/Device Name: Capiox RX Hollow Fiber Oxygenator with/without Hardshell Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTN, DTR, DTP
Dated: November 4, 2015
Received: November 5, 2015

Dear Tierra Brown:

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". The signature is written in a cursive style and is positioned above the printed name.

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® RX Oxygenator/Reservoir

Indications for Use	
510(k) Number	Unknown at time of Submission
Device Name	Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir
Indications for Use	<p>Indications for Use as presented in the Instructions for Use:</p> <p>The CAPIOX RX is intended to be used during open heart surgical procedures requiring cardiopulmonary bypass for periods up to 6 hours. The CAPIOX RX25 is used with patients when required blood flow rate will not exceed 7 L/min. The CAPIOX RX15 is for use with patients when required blood flow rate will not exceed 5 L/min if using product codes CX*RX15RW30 or CX*RX15RE30). The CAPIOX RX Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedure, in post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.</p> <p>Indications for Use as described in the 510(k):</p> <p>The CAPIOX® RX Hollow Fiber Oxygenators with/without Hardshell Reservoir are 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.</p> <p>The integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.</p> <p>The (detachable) hardshell reservoir(s) is (are) used to store blood during extra-corporeal circulation from both venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). 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 reservoir may also be used for Post-Operative Chest Drainage Procedures.</p> <p>The CAPIOX® RX Oxygenators with/without Hardshell Reservoirs can be used in procedures lasting up to 6 hours.</p> <p>The CAPIOX® RX15 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).</p> <p>The CAPIOX® RX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.</p>

Prescription Use XX
(Part 21 CFR 801 Subpart D)

OR
(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)



SECTION 5 – 510(k) Summary
Capiox® RX Oxygenator/Reservoir

5.1 Submitter Information	
Date of Preparation	November 3, 2015
Name	Terumo Cardiovascular Systems Corporation
Address	125 Blue Ball Road Elkton, MD 21921
Establishment Registration Number	1124841
Name of Contact Person	Tierra A. Brown, MSRA, RAC
Contact Person's Title	Regulatory Affairs Specialist
Phone Number	800-262-3304 ext. 7021
Fax Number	410-392-7171
Email	tierra.brown@terumomedical.com



SECTION 5 – 510(k) Summary
Capiox® RX Oxygenator/Reservoir

5.2 Name of Device	
Device Type	Blood Oxygenator with and/or without Blood Reservoir Defoamer Heat Exchanger
Device Common Name	Blood Reservoir Blood Gas Oxygenator Defoamer Heat Exchanger
Device Trade Name	Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir
Predicate Device	Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir; Cleared by FDA with K130333
Classification Regulation	Reservoir: 21 CFR § 870.4400 Oxygenator: 21 CFR § 870.4350 Defoamer: 21 CFR § 870.4230 Heat Exchanger: 21 CFR § 870.4240
Device Risk Classification	Reservoir: Class II Oxygenator: Class II Defoamer: Class II Heat Exchanger: Class II
FDA Product Codes	Reservoir: DTN Oxygenator: DTZ Defoamer: DTP Heat Exchanger: DTR
Reason for 510(k) Submission	Modification to Hardshell Reservoir
Substantial Equivalence Statement	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 predicate device.



SECTION 5 – 510(k) Summary
Capiox® RX Oxygenator/Reservoir

Device Information

5.3 Intended Use:

The intended use remains the same for the modified device and predicate device.

The CAPIOX® RX Hollow Fiber Oxygenators with/without Hardshell Reservoir are 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 integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The (detachable) hardshell reservoir(s) is (are) used to store blood during extra-corporeal circulation from both venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). 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 reservoir may also be used for Post-Operative Chest Drainage Procedures.

The CAPIOX® RX Oxygenators with/without Hardshell Reservoirs can be used in procedures lasting up to 6 hours.

The CAPIOX® RX15 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® RX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

5.4 Principles of Operation and Technology:

The principles of operation and technology remain the same for the modified device and predicate device.

The modified and predicate Capiox® RX device oxygenator utilizes a 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 wound 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® RX device 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 blood, the modified and predicate Capiox® RX Reservoir relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.



SECTION 5 – 510(k) Summary
Capiox® RX Oxygenator/Reservoir

5.5 Design and Materials:

The design of the modified and predicate Capiox® RX devices both utilize an integrated oxygenator/heat exchanger module that provides for temperature control of blood as it enters the oxygenation phase. Each of the devices also utilizes a hardshell reservoir that is used to collect and store blood during a cardiopulmonary bypass procedure. The reservoirs each provide filtration of venous and cardiotomy blood as it enters the reservoir.

With respect to the design of the Oxygenator, the design of the modified Capiox® RX 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.

Differences in the design of the Capiox® RX devices are as follows:

- The *design* of the modified Capiox® RX device will include:
 - flared venous inlet drop tubes
 - The RX15 3-Liter Reservoir's drainage cage, that houses the flared venous inlet drop tubes, will be modified
 - A full-length graduated side scale label (decal)
 - A modified 1/4" x 3/8" winged adapter (adapter is for the RX15 3-Liter Reservoir only)
- The intent of the flared venous inlet drop tubes is to help minimize air emboli generation in the venous section of the reservoir.
- The intent of the modified RX15 3-Liter Reservoir's drainage cage is to accommodate the modified flared venous inlet drop tubes.
- The full-length graduated side scale label (decal) enhancement offers greater visibility of blood volume during cardiopulmonary bypass.
- The modified 1/4" x 3/8" winged adapter (adapter for RX15 3-Liter Reservoir only) is used to provide attachment to the 1/4" arterial and venous line connections.
- The *design* of the predicate Capiox® RX device has:
 - straight venous inlet drop tubes
 - The RX15 3-Liter Reservoir's drainage cage is the original size from initial FDA clearance.
 - A half-length graduated side scale label (decal)
 - A 1/4" x 3/8" adapter

Difference in the materials of the Capiox® RX devices are as follows:

- The *materials* used in the construction of the modified Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir device's venous inlet drop tubes along with the auxiliary drop tube, quick disconnect tubing, sampling manifold tubing, and purge line tubing will be PVC tubing with Tris-(2-Ethylhexyl) Trimellitat, identified as TOTM plasticizer.¹
- The *materials* used in the construction of the predicate Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir device's venous inlet drop tubes along with the auxiliary drop tube, quick disconnect tubing, sampling manifold tubing, and



SECTION 5 – 510(k) Summary
Capiox® RX Oxygenator/Reservoir

Device Information

5.5 Design and Materials *continued*:

- purge line tubing is PVC tubing with Di-(2-ethylhexyl) phthalate, identified as DEHP plasticizer.
- The intent of the PVC tubing plasticizer change to TOTM plasticizer is to address potential safety concerns associated with the use of DEHP as a plasticizer.

The *materials* used in the construction of the modified and predicate Capiox® RX Hollow Fiber Oxygenator/Hardshell Reservoir devices include, but are not limited to, nylon, polycarbonate, silicone, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene and X-Coating™.

Terumo Cardiovascular Systems 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.

5.6 Performance Evaluations:

Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the modified Capiox® RX device to the predicate Capiox® RX device. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Air Handling Performance
- Hemolysis
- Venous Reservoir Pressure Drop
- Venous Defoaming
- Leak Testing
- Winged Adapter Circulation Testing
- 3-Liter Drainage Cage Dimensional Testing
- Connections Testing
- Package Testing
- Aged Evaluation

¹ PVC tubing with Tris-(2-Ethylhexyl) Trimellitate, identified as TOTM plasticizer, is used with Terumo's Capiox® FX15 Advance Oxygenator with Integrated Filter and Hardshell Reservoir, K151389.



SECTION 5 – 510(k) Summary
Capiox® RX Oxygenator/Reservoir

Device Information

5.7 Substantial Equivalence Comparison:

In demonstrating substantial equivalence of the modified Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir to the predicate Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir, Terumo has considered the following aspects to ensure equivalence between the predicate and the subject devices:

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

5.8 Substantial Equivalence Statement:

The modified Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir is *substantially equivalent* in intended use, target population, duration of use, labeling, design, materials, principles of operation and technology, and performance to the predicate Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir. Any noted differences between the modified device and the predicate devices do not raise new issues of safety and effectiveness.

5.9 510(k) Summary Conclusion

Conclusion

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the modified Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir is *substantially equivalent* to the predicate Capiox® RX Hollow Fiber Oxygenator with/without 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.