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

December 02, 2015

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

Re: K153143
Trade/Device Name: Capiox Advance Hardshell Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN, DTP
Dated: October 22, 2015
Received: October 30, 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,

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® Advance Hardshell Reservoir

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

Device Name: Capiox® Advance Hardshell Reservoir

Indications for Use:

The Capiox® Advance Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return 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 Hardshell Reservoir contains X-Coating, which is intended to reduce platelet adhesion on the surfaces of the device.

The device may be used for procedures lasting up to 6 hours.

Prescription Use (Part 21 CFR 801 Subpart D)	XX	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)

SECTION 5 – 510(k) Summary
Capiox® Advance Hardshell Reservoir

Submitter Information	
Date of Preparation	October 22, 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 (x7021)
Fax Number	410-392-7171
Email	tierra.brown@terumomedical.com

Device Information	
Device Classification Type	Cardiopulmonary Bypass Blood Reservoir (Code DTN) Cardiopulmonary Bypass Defoamer (Code DTP)
Device Common Name	Blood Reservoir Defoamer
Device Trade Name	Capiox® Advance Hardshell Reservoir
Predicate Device	Capiox® RX Hardshell Reservoir; Cleared by FDA with K130359
Classification Regulation	Cardiopulmonary Bypass Reservoir 21 CFR § 870.4400 Cardiopulmonary Bypass Defoamer 21 CFR § 870.4230
Device Risk Classification	Cardiopulmonary Bypass Reservoir - Class II Cardiopulmonary Bypass Defoamer – Class II
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.

Intended Use:

The intended use remains the same as the intended use for the predicate device cleared with submission K130359. There have been no changes to the indications or intended use of the subject device as a result of the modifications.

The Capiox® Advance Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return 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 Hardshell Reservoir contains X-Coating, which is intended to reduce platelet adhesion on the surfaces of the device.

The device may be used for procedures lasting up to 6 hours.

Principles of Operation and Technology:

The principles of operation and technological characteristics remain the same as that of the predicate device cleared with submission K130359. There have been no changes to the fundamental scientific technology of the subject device.

The Capiox® Advance Hardshell Reservoir device and the predicate Capiox® RX Hardshell Reservoir device are both used as a blood storage devices during and after cardiopulmonary bypass procedures. Venous blood enters the reservoir via gravity, or by way of external vacuum that may be applied to the reservoir.

Venous blood that is drawn from the patient enters the device via the venous blood inlet port. The blood passes through a defoamer to remove air bubbles from the blood and through a filter to remove particulates from the blood.

Blood may also be suctioned into the reservoir from the cardiotomy field. This blood enters the device through the cardiotomy blood suction ports. The blood passes through a defoamer to remove air bubbles from the blood and through a filter to remove particulates from the blood.

Blood exits the device via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

Design and Materials:

The *design* of the Capiox® Advance Hardshell Reservoir is comprised of a hardshell casing that serves as a blood containment system within the bypass circuit. The upper portion of the

reservoir consists of a hardshell lid assembly that contains the necessary inlet ports and vent ports. It contains a rotatable venous blood inlet port. The total capacity of the reservoir is 4000mL.

The venous section of the reservoir contains a filter for particulate matter removal and a defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter for particulate matter removal and a defoamer to facilitate air bubble removal.

Differences in the *design* of the two Reservoirs are as follows:

- The *design* of the Capiox® Advance Hardshell Reservoir device will include a curved venous inlet port and flared venous inlet drop tubes. The *design* of the predicate Capiox® RX Hardshell Reservoir device has an angled venous inlet port and straight venous inlet drop tubes. The intent of the curved venous inlet port is to improve air handling performance of the port. A curved design is more conducive to smooth flow than an angled design. The intent of the flared venous inlet drop tubes modification is to help minimize air emboli generation in the venous section of the reservoir.
- The Capiox® Advance Hardshell Reservoir device has a full-length graduated side scale label (decal). The predicate Capiox® RX Hardshell Reservoir device has a half-length graduated side scale label (decal). The full-length graduated side scale label (decal) enhancement offers greater visibility of blood volume during cardiopulmonary bypass.
- The Capiox® Advance Hardshell Reservoir device has a minimum operating volume of 150mL. The predicate Capiox® RX Hardshell Reservoir device has a minimum operating volume of 200mL. The minimum operating volume is lowered to 150mL to facilitate lower blood volumes during cardiopulmonary bypass.

Difference in the *materials* of the two Reservoirs are as follows:

The *materials* used in the construction of the Capiox® Advance Hardshell Reservoir include, but are not limited to, nylon, polycarbonate, silicone, polyvinyl chloride, polyurethane, polyester, polypropylene, polymethyl methacrylate, polyhydroxyethyl methacrylate, polyethylene, and X-Coating™. PVC tubing with TOTM plasticizer has been cleared for use with Terumo's FX15 Advance Oxygenator with Integrated Filter and Hardshell Reservoir, K151389.

- The *material* used in the construction of the Capiox® Advance Hardshell Reservoir device's venous inlet drop tubes and auxiliary tubing (blood-contacting) will be PVC tubing with Tris-(2-Ethylhexyl) Trimellitate, identified as TOTM plasticizer[1]. The *material* used in the construction of the predicate Capiox® RX Hardshell Reservoir device's venous inlet drop tubes and auxiliary tubing (blood-contacting) is PVC tubing with Di-(2-ethylhexyhl) phthalate, identified as DEHP plasticizer.
- The intent of the PVC tubing plasticizer change to TOTM plasticizer is to address growing potential safety concerns associated with DEHP and to address increasing concerns related to the use of DEHP.

Terumo Cardiovascular Systems concludes that the differences between the subject 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.

[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.

Performance Evaluations:

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

- Air Handling Performance
- Hemolysis
- Venous Filter Dynamic Hold Up and/or Pressure Drop
- Vacuum Testing (Product Integrity, Large Venous Port-O-Ring Seal)
- Burst, Leak, Circulation, and/or Pull Testing to Evaluate Venous Port and Tubing Connection Integrity
- Pre-Connect Evaluation
- Package Testing

Substantial Equivalence Comparison:

In demonstrating substantial equivalence of the Capiox® Advance Hardshell Reservoir to the predicate Capiox® RX 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

Substantial Equivalence Statement:

The Capiox® Advance Hardshell Reservoir is *substantially equivalent* to the predicate Capiox® RX Hardshell Reservoir in intended use, duration of use, design, materials, principles of operation and technology, and performance and specifications. Any noted differences between the subject device and the predicate device do not raise new issues of safety and/or effectiveness.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Capiox® Advance Hardshell Reservoir is *substantially equivalent* in intended use, duration of use, design, materials, principles of operation and technology, and performance and specifications to the predicate Capiox® RX 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.