June 22, 2018

Terumo Cardiovascular Systems Corporation
Adam Pickholtz
Manager, Regulatory Affairs
125 Blue Ball Road
Elkton, Maryland 21921

Re: K180950
Trade/Device Name: Terumo Capiox NX19 Oxygenator with Reservoir (east Orientation), Terumo Capiox NX19 Oxygenator with Reservoir (west Orientation), Terumo Capiox NX19 Oxygenator (east Orientation), Terumo Capiox NX19 Oxygenator (west Orientation)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTM, DTN, DTP
Dated: April 10, 2018
Received: April 11, 2018

Dear Adam Pickholtz:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel -S

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® NX19 Oxygenator with Integrated Arterial Filter

510(k) Number (if known): K180950

Device Name: **Capiox® NX19 Oxygenator with Integrated Arterial Filter**

Indications for Use:
The Capiox® NX19 Oxygenator with Integrated Arterial Filter and UltraPrime™ Technology is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of adult and small adult patients during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filter 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 4-liter reservoir may be used for Vacuum Assisted Drainage procedures and Post-Operative Chest Drainage Procedures.

The Capiox® NX19 Oxygenator with Integrated Arterial Filter and UltraPrime™ Technology is for use with patients when the required blood flow rate will not exceed 8.0 L/min.

The Capiox® NX19 Oxygenator with Integrated Arterial Filter and UltraPrime™ Technology can be used in procedures lasting up to 6 hours.

Prescription Use	XX	OR Over-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)

K180950

Submitter Information

This submission was prepared in March 2018 by**:**

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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 Name &Classifications

Proprietary Name	Classification Name	Common Name
Capiox® NX19 Oxygenator with Integrated Arterial Filter	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
	Cardiopulmonary Bypass (Code: DTP)	Defoamer
	Defoamer	

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® FX25 Advance Oxygenator with Integrated Arterial Filter and Hardshell Reservoir – K151791

Reference Devices:

- Sorin Inspire 8F Oxygenator with Integrated Arterial Filter and Hardshell Reservoir-K121536

- Terumo Capiox NX19 Oxygenator with Integrated Arterial Filter- K172071

Intended Use

The Capiox® NX19 Oxygenator with Integrated Arterial Filter and UltraPrime™ Technology is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of adult and small adult patients during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filter 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 4-liter reservoir may be used for Vacuum Assisted Drainage procedures and Post-Operative Chest Drainage Procedures.

The Capiox® NX19 Oxygenator with Integrated Arterial Filter and UltraPrime™ Technology is for use with patients when the required blood flow rate will not exceed 8.0 L/min.

The Capiox® NX19 Oxygenator with Integrated Arterial Filter and UltraPrime™ Technology can be used in procedures lasting up to 6 hours.

Principles of Operation and Technology

The Capiox® NX19 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 Capiox® NX19 Oxygenator device has an integrated heat exchanger that is comprised of Polyethylene Terephthalate tubes arranged in a cylindrical shape. The circulating blood contacts the exterior surface of these tubes. Temperature-controlled water distributed from an external water bath fills the interior of the tubes. The heat exchanger material permits heat transfer to occur across the walls of the heat exchanger tubes to achieve the necessary temperature of the circulating blood.

The Capiox® NX19 Oxygenator device can be operated at flow rates up to 8 liters per minute (l/min) and at a minimum flow rate of 2.0 liters per minute (l/min) or 0.5 liters per minute (l/min) for up to 2 hours.

The integrated arterial filter of the Capiox® NX19 Oxygenator device relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

The operation and technology employed by the new NX19 Oxygenator device are consistent with the operation and technology of the predicate FX25 Advance Oxygenator device.

Design and Materials

The primary differences in the design and materials between the Capiox® NX19 Oxygenator and the predicate device are:

- Reduction in the diameter of the polypropylene oxygenator fibers vs. the predicate;
- Higher Molecular weight of Polymethoxyethyl acrylate (PMEA) solution vs. the predicate;
- Difference in the materials of construct of the heat exchanger – plastic vs stainless steel;
- The NX19 has a lower priming volume vs. the predicate device.
- The NX19 utilizes pre-heat exchanger vent fiber to facilitate air removal during priming

Reduction in diameter of the oxygenator fibers:

The Capiox® NX19 Oxygenator utilizes an oxygenator fiber that has a diameter approximately 40% smaller than that of the predicate device. This smaller diameter allows for a larger percentage of the blood in the oxygenator to be in contact with the surface area of the fibers. By increasing this contact, similar gas exchange performance can be achieved with a lower blood volume. The smaller fiber diameter allows the NX19 oxygenator to have a surface of approximately 1.9m^2 compared to the approximately 2.5m^2 surface area of the predicate device while still achieving equivalent gas exchange performance.

Higher Molecular weight of Polymethoxyethyl acrylate (PMEA) solution:

The X-Coating™ solution utilized to coat the NX19 Oxygenator varies from the solution that is used to coat the predicate device. The NX19 X-Coating™ solution is Polymethoxyethyl acrylate (PMEA). This solution has a molecular weight of 400kDa. The solution for the predicate device is also PMEA solution, but has a lower molecular weight. The predicate X-Coating™ has a molecular weight of 85kDa. This increased molecular weight with the NX19 device allows for increased stability of the coating when applied to the polypropylene fibers of the oxygenator bundle.

Difference in the materials of construct of the heat exchanger – plastic vs stainless steel:

The material and the surface area of the heat exchanger in the Capiox® NX19 Oxygenator varies from the predicate device. The heat exchanger tubes in the NX19 Oxygenator are made of Polyethylene Terephthalate (PET) plastic material. This PET material differs from the stainless steel bellows in the heat exchanger of the predicate device. The surface area of the PET heat exchanger tubes is 0.43m^2 in the NX19, which is a larger surface area than the 0.2m^2 in the predicate FX25. This increased surface area ensures that adequate (equivalent) heat exchange is achieved.

The NX19 has a lower priming volume vs. the predicate device:

The prime volume of the Capiox® NX19 Oxygenator is 185mL, which is lower than the 260mL priming volume of the predicate FX25 device. The reduced prime volume helps reduce the amount of blood that needs to be removed from a patient which, in turn, reduces the need for hemo-dilution.

Both the new NX19 Oxygenator and the predicate FX25 Oxygenator are comprised of the same generic materials, and they both feature common design characteristics. The notable differences in materials and design (as identified above) do not raise any issues of safety or effectiveness. Both devices are deemed to be clinically acceptable.

The NX19 utilizes pre-heat exchanger vent fiber to facilitate air removal during priming
To facilitate air removal during priming, the NX19 utilizes pre-HE microporous fiber, oxygenator microporous fiber and a purge port. The FX25 predicate device relies on oxygenator microporous fiber and a purge port for facilitation of air removal during priming (without the presence of pre-HE microporous fiber).

Performance:
Terumo Cardiovascular Systems has conducted in-vitro performance evaluations for the purpose of demonstrating that the Capiox® NX19 Oxygenator is substantially equivalent to the predicate the Capiox® FX25 Advance Oxygenator. Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate device. Substantial equivalence is demonstrated with the following in-vitro performance evaluations:

- Gas Transfer and Pressure Drop Performance
- Heat Exchanger Performance
- Hemolysis Performance
- Air Removal Performance
- Capnography Assessment
- Connection Strength of Ports
- Filtration Efficiency
- Mechanical Integrity
- Luer Port Assessment
- NX Blood Compatibility

In addition to the verification testing listed above conducted on the oxygenator, the reservoir testing included in K151791 supports the increased maximum flow rate of the reservoir. The reservoir to be offered with the NX19 oxygenator is the EXACT SAME RESERVOIR that is offered with the FX25 and was cleared in K151791. The verification testing listed below was conducted on the reservoir and presented in K151791. This testing is also presented in Appendix D of this submission:

- Testing of Air Handling
- Testing of Hemolysis
- Testing of Venous Defoaming
- Testing of Pressure Drop
- Testing of Clotting
- Testing of Connection Strength

The Terumo Cardiovascular Systems Corporation Capiox® NX19 Oxygenator exhibits performance features that are deemed “substantially equivalent” to the predicate Capiox® FX25 Advance Oxygenator - K151791.

In addition to the above listed predicate device, Terumo has identified the Sorin Inspire 8F Oxygenator with integrated arterial filter and hardshell reservoir (K121536) and the Terumo Capiox NX19 Oxygenator with Integrated Arterial Filter (K172071) as reference devices for performance tests and other applicable testing. Because these devices share similar technological characteristics to the subject device, Terumo felt it was appropriate to use the Inspire 8F and Capiox NX19 as reference devices when setting the acceptance criteria for performance testing and other relevant tests.

The Terumo Cardiovascular Systems Corporation Capiox® NX19 Oxygenator exhibits performance features that are deemed "substantially equivalent" to the reference devices.

Labeling

The subject Capiox® NX19 Oxygenator device and the predicate Capiox® FX25 Advance device are offered to the user with adequate Instructions for Use and other product labeling as required by regulation. While the labeling for the NX19 will differ from that of the FX25 with respect to content, the same required elements are present for both devices. Less information will be present on the product label for the NX19 as compared to the FX25. However, the information removed from the product label will be incorporated into a new pouch label. The contents of the box labels will remain the same. Refer to Section 12 – Labeling for more details.

Substantial Equivalence Statement

The Terumo Cardiovascular Systems Corporation Capiox® NX19 Oxygenator device (with 4-liter Reservoir) and the predicate Capiox® FX25 Advance device (with 4-liter Reservoir) are substantially equivalent in intended use, principles of operation and technology, design, materials, performance and labeling. The noted differences between the subject devices and the predicate devices do not raise new issues of safety and effectiveness.

The intended use and product indications of the new NX19 Oxygenator device are consistent with those of the predicate FX25 Advance Oxygenator device.

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 Guidance Document (6/16/16): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process." [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® NX19 Oxygenator device with 4-liter Reservoir is substantially equivalent to the predicate (K151791) Capiox® FX25 Advance device with 4-liter Reservoir with respect to intended use, principles of operation and technology, design, materials, performance, and labeling. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.