December 17, 2021

Qura S.r.l.
Raffaella Tommasini
QA&RA Director
Via di Mezzo, 23
Mirandola, Modena 41037
Italy

Re: K203424
Trade/Device Name: Quantum Perfusion Blood Oxygenator ECC VT200-E1, Quantum Perfusion Blood Oxygenator ECC VT200-E2, Quantum Perfusion Blood Oxygenator ECC VT160-E1, Quantum Perfusion Blood Oxygenator ECC VT160-E2
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: November 18, 2021
Received: November 22, 2021

Dear Raffaella Tommasini:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203424

Device Name
Quantum Perfusion Blood Oxygenator ECC VT200-E2

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator ECC VT200-E2 is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use.

Devices are intended for adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203424

Device Name
Quantum Perfusion Blood Oxygenator ECC VT200-E1

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator ECC VT200-E1 is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure and temperature during the procedure. The device is limited to 6 hours of use.

Devices are intended for adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203424

Device Name
Quantum Perfusion Blood Oxygenator ECC VT160-E2

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator ECC VT160-E2 is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use.

Devices are intended for adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203424

Device Name
Quantum Perfusion Blood Oxygenator ECC VT160-E1

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator ECC VT160-E1 is a diffusion membrane oxygenator, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure and temperature during the procedure. The device is limited to 6 hours of use.

Devices are intended for adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

I. SUBMITTER

Submitter Name:	Qura S.r.l.
Submitter Address:	Via di Mezzo, 23 41037 Mirandola (MO) Italy
Contact Person:	Raffaella Tommasini, QA&RA Director – Qura s.r.l.
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Fax:	+39 0535 1803051
Date Summary Prepared:	December 17th, 2021

II. DEVICE

Proprietary Name:	Quantum Perfusion Blood Oxygenator ECC VT200-E1, Quantum Perfusion Blood Oxygenator ECC VT200-E2, Quantum Perfusion Blood Oxygenator ECC VT160-E1, Quantum Perfusion Blood Oxygenator ECC VT160-E2
Common Name:	Blood Oxygenator
Classification Name:	Oxygenator, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DTZ
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE AND REFERENCE DEVICES

Predicate device:

Trade Name:	QUADROX-iD Adult
Registered Establishment Name:	MAQUET CARDIOPULMONARY AG
Regulation Number:	870.4350
Regulation Name:	Cardiopulmonary Bypass Oxygenator
Regulatory Class:	II
Product Code:	DTZ
510(k) Number	K150267

Reference device:

Trade Name:	EOS PMP
Registered Establishment Name:	Sorin Group Italia S.r.l.
Regulation Number:	870.4350
Regulation Name:	Cardiopulmonary Bypass Oxygenator
Regulatory Class:	II
Product Code:	DTZ
510(k) Number	K150489

IV. DEVICE DESCRIPTION

The Quantum Perfusion Blood Oxygenator ECC (acronym VT-E) diffusion membrane device is designed to oxygenate blood and remove carbon dioxide from venous blood during cardiac surgical procedures requiring cardiopulmonary bypass for a maximum duration of 6 hours..

Blood enters the oxygenator through the blood inlet connector, flows through a blood chamber, touching the outer surface of hollow fibers membrane; while the sweep gas flows into the hollow fiber membrane. The hollow fibers are made of Polymethylpentene (PMP). In this chamber, carbon dioxide moves from the blood to the gas compartment, while oxygen enters into the red blood cells. Then, blood exits the oxygenator with the desired level of oxygen content and saturation, and carbon dioxide content. Sweep gas composition and flow rate are used to control saturation, and oxygen and carbon dioxide content of blood at the outlet of the oxygenator.

The device is non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a single box.

All the device surfaces in contact with blood are treated with a phosphorylcholine-based biocompatible coating.

Significant physical and performance characteristics:

	CODE			
Characteristics	**VT200-E1**	**VT200-E2**	**VT160-E1**	**VT160-E2**
Blood contact materials	Tritan copolyester Polymethylpentene (PMP) Polyurethane (PU) Coating: phosphorylcholine			
Maximum operating pressure - blood side	760 mmHg / 100 kPa / 1 bar / 14.5 psi			
Static priming volume (ml)	195		160	
Exchange surface area (m^2)	1.75		1.45	
Blood flow (l/min)	1-7		0.5-5	
Maximum gas flow (l/min)	10			
Connections - blood side (IN/OUT)	3/8” (9.525mm)			
Arterial sampling	Luer Lock			
Purge line	Luer Lock			
Connections - gas side IN OUT	CPC APC profile 1/4'' (6.35mm) and Luer Lock			
Temperature probe - Blood OUT	YSI 400	NA	YSI 400	NA
Blood OUT pressure sensor - Range	-200 to 600 mmHg / -27 to 80 KPa / -0.27 to 0.8 bar / -3.8 to 11.6 psi			

Table 5-1 –Main characteristics

Additional information have been provided in Section 10 of K203424 submission.

V. INTENDED USE / INDICATIONS FOR USE

Quantum Perfusion Blood Oxygenator ECC VT200-E1 and Quantum Perfusion Blood Oxygenator ECC VT160-E1 are diffusion membrane oxygenators, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure and temperature during the procedure. The device is limited to 6 hours of use.

Quantum Perfusion Blood Oxygenator ECC VT200-E2 and Quantum Perfusion Blood Oxygenator ECC VT160-E2 are diffusion membrane oxygenators, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use.

Devices are intended for adult patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

An extensive and complete comparison between Quantum Perfusion Blood Oxygenator ECC (all variants) and the predicate device has been conducted. Based on the safety, performance data, technological characteristics, and the indications for use of the predicate device:

- **Quantum Perfusion Blood Oxygenator ECC (all variants)** are considered substantially equivalent to the legally marketed predicate device QUADROX-iD Adult Oxygenator (K150267) since the intended use, main blood-contact materials and technological characteristics are the same.

In addition, in terms of performance:

- **VT200-E1 and VT200-E2 devices** are considered substantially equivalent to the legally marketed predicate device QUADROX-iD Adult Oxygenator (K150267).
- **VT160-E1 and VT160-E2 devices** are considered substantially equivalent to the legally marketed reference predicate device EOS-PMP (K150489).

A summary of the technological characteristics of Quantum Perfusion Blood Oxygenator ECC to those of the predicate/reference device has been given in table below.
Additional information have been provided in Section 12 of K203424 submission.

Device	Proposed Device – Quantum Perfusion Blood Oxygenator ECC	Predicate Device – Maquet Quadrox-iD Adult Oxygenator	Reference Predicate Device – Sorin Group Italia EOS PMP
Name	Quantum Perfusion Blood Oxygenator ECC VT200-E1 Quantum Perfusion Blood Oxygenator ECC VT200-E2 Quantum Perfusion Blood Oxygenator ECC VT160-E1 Quantum Perfusion Blood Oxygenator ECC VT160-E2	QUADROX-iD Adult	EOS PMP
510(k) Number	K203424	K150267	K150489
Regulation #	870.4350		
Regulation Name	Cardiopulmonary Bypass Oxygenator		
Product Code	DTZ		
Classification	II		
Indication for Use	Quantum Perfusion Blood Oxygenator ECC VT200-E1 and Quantum Perfusion Blood Oxygenator ECC VT160-E1 are diffusion membrane oxygenators, designed to oxygenate and remove carbon dioxide from venous blood blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure and temperature during the procedure. The device is limited to 6 hours of use. Quantum Perfusion Blood Oxygenator ECC VT200-E2 and Quantum Perfusion Blood Oxygenator ECC VT160-E2 are diffusion membrane oxygenators, designed to oxygenate and remove carbon dioxide from venous blood during cardiac surgery requiring cardiopulmonary bypass and to measure blood pressure during the procedure. The device is limited to 6 hours of use. Devices are intended for adult patients.	The QUADROX-iD Adult oxygenator is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide from the blood and regulates the blood temperature. The application duration is limited to 6 hours. Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.	The device is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters/minute. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The device is intended to be used for 6 hours or less.
Main Contacting Materials	Fiber: Polymethylpentene (PMP) Coating: Phosphorylcholine Housing: Tritan Sensor: Polycarbonate and silicone-based protective gel	Fiber: Polymethylpentene (PMP) Coating: Softline (synthetic polymer-based coating) Housing: Polycarbonate (PC)	Fiber: Polymethylpentene (PMP) Coating: Phosphorylcholine Housing: Polycarbonate Heat exchanger: Stainless steel

Device	Proposed Device – Quantum Perfusion Blood Oxygenator ECC	Predicate Device – Maquet Quadrox-iD Adult Oxygenator	Reference Predicate Device – Sorin Group Italia EOS PMP
		Heat exchanger: thermoplastic polyurethane (TPU)	
Blood side Connector Type	3/8" (9.525mm)		
Max flow rate [l/min] VT200-E1, VT200-E2 VT160-E1, VT60-E2	 7 5	7	 5
Exchange surface [m^2] VT200-E1, VT200-E2 VT160-E1, VT60-E2	 1.75 1.45	1.8	 1.2
Static Priming Volume [ml]	 195 160	215	 150
Presence of sensor	Pressure sensors located integrated in the blood out connector.	Not present	Not present
Single-use	Yes	Yes	
Sterile Condition	EtO Sterile	EtO Sterile	

Table 5-2 – Comparative Data

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

In-vitro testing was performed to demonstrate the product's substantial equivalence with the predicate device and also to comply with user needs and safety and effectiveness requirements. Testing supplied in the 510(k) Notification includes biocompatibility evaluation, mechanical and performance verification, labeling and Instructions for Use (IFU), verification and validation tests.

All testing passed by meeting the established requirements set for the use of the devices. The following data were provided:

- Performance tests, according to applicable special controls according to ISO 7199, 21 CFR §870.4350 and "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff", dated November 13, 2000:
    - Operating priming volume;
    - Device pressure Drop;
    - Gas Transfer Performances;
    - Mechanical Blood Cell Damage;
    - Ease of Prime and Air handling;
    - Filtration efficiency;
    - Temperature probe and Pressure sensor verification;
    - Mechanical Integrity;
    - Mechanical resistance of connectors;
    - Coating coverage and durability.
- Evaluation of product shelf life, including product's sterility according to EP/UPS requirements;
- Validation of the EtO Sterilization process, according to ISO 11135:2014 [Recognition Nr.: 14-452];
- Packaging Validation tests according to ISO 11607-1:2019 [Recognition Nr.: 14-530];
- Biocompatibility of the finished product, according to International Standard ISO 10993-1:2018 [Recognition Nr. 2-258] and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Animal Study

No animal studies have been performed except for mandatory biocompatibility tests according to International Standard ISO 10993-1:2018 [Recognition Nr. 2-258] and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

CLINICAL TESTING

No clinical data have been included in the current Traditional 510(k) submission to support substantial equivalence to legally marketed predicate devices.

VIII. CONCLUSIONS

Based on the indications for use, main technological characteristics and results of non-clinical testing, the subject devices have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to legally marketed predicate (K150267) and reference (K150489) devices.