January 28, 2022

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

Re: K212341
Trade/Device Name: Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U, Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U,Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: December 23, 2021
Received: December 29, 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)*
K212341

Device Name
Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U

Indications for Use *(Describe)*

Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U is a diffusion membrane oxygenator, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass, to measure blood pressure and temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli. The device is limited to 6 hours of use.
Device is 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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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)*
K212341

Device Name
Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U is a diffusion membrane oxygenator, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass, to measure temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli.The device is limited to 6 hours of use.
Device is 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)*
K212341

Device Name
Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U

Indications for Use *(Describe)*

Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U is a diffusion membrane oxygenator, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass, to measure blood pressure and temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli. The device is limited to 6 hours of use.
Device is 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.

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)*
K212341

Device Name
Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U is a diffusion membrane oxygenator, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass, to measure temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli.The device is limited to 6 hours of use.
Device is 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.

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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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Date Summary Prepared:	December 23rd, 2022

II. DEVICES

Proprietary Name:	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF VT160 – C2U, Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U.
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)
510(k) Number:	K212341

III. PREDICATE AND REFERENCE DEVICES

Predicate device:

Trade Name:	INSPIRE 8F M Hollow Fiber Oxygenator With Integrated Arterial Filter
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	K180448

Reference device:

Trade Name:	INSPIRE 6F M Hollow Fiber Oxygenator With Integrated Arterial Filter
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	K180448

IV. DEVICE DESCRIPTION

Quantum Perfusion Blood Oxygenator devices (acronym VT-C) consist of an oxygenator with an integrated arterial filter.

The Quantum Perfusion Blood Oxygenator device is designed to provide gas exchange during cardiac surgical procedures requiring cardiopulmonary bypass for a maximum duration of 6 hours.

The device has microporous hollow fibers, made of Polypropylene (PP) and with high gas permeability, that allow gas exchange. The integrated arterial filter provides additional protection against air and solid emboli.

Blood enters the oxygenator through the blood inlet connector, flows through a blood chamber, touching the outer surface of a hollow fiber membrane, exits the oxygenator with the desired level of gas exchange.

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-C1U**	**VT200-C2U**	**VT160-C1U**	**VT160-C2U**
Blood contact materials	Tritan copolyester Polypropylene (PP) Polyurethane (PU) Polyester (PET) Coating: phosphorylcholine			
Maximum operating pressure - blood side	760 mmHg / 100 kPa / 1 bar / 14.5 psi			
Static priming volume (ml)	200		160	
Exchange surface area (m^2)	1.75		1.45	
Blood flow (l/min)	1-8		0.5-6	
Maximum gas flow (l/min)	10			
Connections - blood side (IN/OUT)	3/8” (9.525mm)			
Connections - gas side IN OUT	CPC APC profile 1/4'' (6.35mm), cone and Luer Lock			
Arterial sampling	Luer Lock			
Purge line	Luer Lock			
Cardioplegia connector	Pos Lock			
Arterial filter size: Pore size (µm) Filter surface area (cm^2)	 40 78		 40 60	
Temperature probe - Blood OUT	YSI 400			
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	/	-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

V. INTENDED USE / INDICATIONS FOR USE

Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U and Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U are diffusion membrane oxygenators, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass, to measure blood pressure and temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli. The devices are limited to 6 hours of use.

Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U and Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U are diffusion membrane oxygenators, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass and to measure temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli. The devices are 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 (all variants) and the predicate device has been conducted. Quantum Perfusion Blood Oxygenator devices has the same intended use and operating principle as the predicate and reference devices.

Based on the safety, performance data, technological characteristics, and the indications for use of the predicate device:

- **Quantum Perfusion Blood Oxygenator (all variants)** are considered substantially equivalent to the legally marketed predicate device INSPIRE 8F M (K180448) since the intended use, main blood-contact materials and technological characteristics are the same.

In addition, in terms of performance:

- **VT200-C1U and VT200-C2U devices** are considered substantially equivalent to the legally marketed predicate device INSPIRE 8F M (K180448).
- **VT160-C1U and VT160-C2U devices** are considered substantially equivalent to the legally marketed reference predicate device INSPIRE 6F M (K180448).

A summary of the technological characteristics of Quantum Perfusion Blood Oxygenators to those of the predicate/reference device has been given in table below.

Device	Proposed Device – Quantum Perfusion Blood Oxygenator	Predicate Device – Sorin Group Italia Inspire 8F M	Reference Predicate Device – Sorin Group Italia Inspire 6F M
Name	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U	INSPIRE 8F M Hollow Fiber Oxygenator With Integrated Arterial Filter	N.A.
	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U		INSPIRE 6F M Hollow Fiber Oxygenator With Integrated Arterial Filter
510(k) Number	K212341	K180448	
Regulation #	870.4350	870.4350	
Regulation Name	Cardiopulmonary Bypass Oxygenator	Cardiopulmonary Bypass Oxygenator	
Product Code	DTZ	DTZ	
Classification	II	II	
Indication for Use	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U and Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U are diffusion membrane oxygenators, designed to provide gas exchange during cardiac surgery requiring cardiopulmonary bypass, to measure blood pressure and temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli. The devices are limited to 6 hours of use. Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U and Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U are diffusion membrane oxygenators, designed to provide gas exchange during cardiac surgery requiring	The Inspire 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. Inspire 8F M integrated arterial filter provides additional protection against air and solid emboli. Inspire 8F M is intended to be used for 6 hours or less.	The Inspire 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. Inspire 6F M integrated arterial filter provides additional protection against air and solid emboli. Inspire 6F M is intended to be used for 6 hours or less

Device	Proposed Device – Quantum Perfusion Blood Oxygenator	Predicate Device – Sorin Group Italia Inspire 8F M	Reference Predicate Device – Sorin Group Italia Inspire 6F M
	cardiopulmonary bypass, and measure temperature during the procedure. The integrated arterial filter provides additional protection against air and solid emboli. The devices are limited to 6 hours of use. Devices are intended for adult patients.		
Main Contacting Materials	Fiber: polypropylene (PP) Coating: Phosphorylcholine Arterial filter: polyester (PET) Housing: Tritan Sensor: Polycarbonate and silicone-based protective gel	Fiber: Polypropylene (PP) Coating: Phosphorylcholine Arterial filter: Polyester (PET) Housing: Polycarbonate Heat exchanger: Polyurethane (PU)	
Blood side Connector Type	3/8" (9.525mm)	3/8" (9.525mm)	
Max flow rate [l/min]	VT200-C1U – VT 200-C2U: 8 VT160-C1U – VT160-C2U: 6	8	6
Exchange surface [m^2]	VT200-C1U – VT 200-C2U: 1.75 VT160-C1U – VT160-C2U: 1.45	1.75	1.4
Static Priming Volume [ml]	VT200-C1U – VT 200-C2U: 200 VT160-C1U – VT160-C2U: 160	351	284
Arterial filter cut-off size [µm]	40	38	38
Presence of sensor	Pressure sensors located integrated in the blood out connector (C1U variants only)	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

The following non-clinical testing was performed to support the substantial equivalence of Quantum Perfusion Blood Oxygenators to the legally marketed predicate devices. This testing included biocompatibility evaluation, mechanical and performance verification, labeling and Instructions for Use (IFU), and 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 [Recognition Nr. 3-150], 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.: 14-529];
- 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, technological characteristics, results of non-clinical testing, and comparison to predicate devices, Quantum Perfusion Blood Oxygenators have been shown to be substantially equivalent to legally marketed predicate and reference devices (both covered by K180448).