November 8, 2023

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

Re: K231773
Trade/Device Name: Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: October 10, 2023
Received: October 10, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 M. Gillette -S

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)*
K231773

Device Name
Quantum Perfusion Blood Oxygenator with Intgrated AF and Sensor VT75-C1U

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-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 Adolescent and Transitional Adolescent patients (from 12 to 21 years old age).

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)*
K231773

Device Name
Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U

Indications for Use *(Describe)*
Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U is a diffusion membrane oxygenator, 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 device is limited to 6 hours of use.

Devices is intended for Adolescent and Transitional Adolescent patients (from 12 to 21 years old age).

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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e-mail:	raffaella.tommasini@quramed.com
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Date Summary Prepared:	October 10th, 2023

II. DEVICE

Proprietary Name:	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U Quantum Perfusion Blood Oxygenator with Integrated AF VT75-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)

III. PREDICATE AND REFERENCE DEVICES

Predicate Device

Proprietary Name:	D101 Kids Infant Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir
Common Name:	Hollow Fiber Membrane Oxygenator with Hardshell Cardiotomy/Venous Reservoir
Classification Name:	Oxygenator, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DTZ
510(k) Number:	K072091

Reference Device

Proprietary Name:	Quantum Perfusion Blood Oxygenator devices
Common Name:	Blood Oxygenator
Classification Name:	Oxygenator, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DTZ
510(k) Number:	K212341

IV. DEVICE DESCRIPTION

Quantum Perfusion Blood Oxygenator devices, VT75-C1U and VT75-C2U, 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.

V. INTENDED USE / INDICATIONS FOR USE

Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U

Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-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.

Devices are intended for Adolescent and Transitional Adolescent patients (from 12 to 21 years of age).

Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U

Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U is a diffusion membrane oxygenator, 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 device is limited to 6 hours of use.

Devices are intended for Adolescent and Transitional Adolescent patients (from 12 to 21 years of age).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison between Quantum Perfusion Blood Oxygenator devices, VT75-C1U and VT75-C2U, and the predicate and reference devices has been conducted.

Quantum Perfusion Blood Oxygenator devices have the same operating principle and intended duration as the predicate and reference devices.

Quantum Perfusion Blood Oxygenator VT75-C1U and VT75-C2U devices and primary predicate device have both an intended population regarding pediatric patients. The target population of the D101 Kids device is specific to infant patients (i.e., from 29 days to 2 years of age) and therefore falls in a more critical threshold respect to identified category for subject devices (i.e. Adolescent and Transitional Adolescent, from 12 to 21 years of age).

A summary of the technological characteristics of Quantum Perfusion Blood Oxygenator devices to those of the predicate and reference devices has been given in table below. Additional information are available in Attachment "Substantial Equivalence Comparison" of present "Additional Information" required by the Agency.

Device	Proposed Devices – Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U Qura S.r.l.	Predicate Device – D101 Kids Sorin Group Italia S.r.l.	Reference Devices – Quantum Perfusion Blood Oxygenator Devices Qura S.r.l.
Name	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U	D101 Kids Infant Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir	Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U
	Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U		Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U
510(k) Number	K231773	K072091	K212341
Device description	The Quantum Perfusion Blood Oxygenator device (acronym VT-C) is designed to oxygenate blood and remove carbon dioxide from venous blood during cardiac surgical procedures requiring cardiopulmonary	The D101 KIDS Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir with phosphorylcholine coating (hereafter referred to as the D101 KIDS) is a high efficiency infant microporous hollow fiber membrane oxygenator integrated	The Quantum Perfusion Blood Oxygenator device (acronym VT-C) is designed to oxygenate blood and remove carbon dioxide from venous blood during cardiac surgical procedures requiring cardiopulmonary

Device	Proposed Devices – Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U Qura S.r.l.	Predicate Device – D101 Kids Sorin Group Italia S.r.l.	Reference Devices – Quantum Perfusion Blood Oxygenator Devices Qura S.r.l.
	bypass for a maximum duration of 6 hours. The Quantum Perfusion Blood Oxygenator device has an integrated arterial filter and can be operated up to 2,5 liters per minutes.	with an heat exchanger and connected to an hardshell cardiotomy/venous reservoir.	bypass for a maximum duration of 6 hours. The Quantum Perfusion Blood Oxygenator device has an integrated arterial filter and can be operated up to 6 liters per minutes (VT160 variants).
Regulation #	21 CFR §870.4350	21 CFR §870.4350	21 CFR §870.4350
Regulation Name	Cardiopulmonary Bypass Oxygenator	Cardiopulmonary Bypass Oxygenator	Cardiopulmonary Bypass Oxygenator
Product Code	DTZ	DTZ	DTZ
Classification	II	II	II
Indication for Use	VT75-C1U Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-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. VT75-C2U Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U is a	The D101 KIDS Infant Hollow Fiber Membrane Oxygenator is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 2.5 liters/minute. It provides oxygenation and carbon dioxide removal from venous or suctioned 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 venous reservoir is intended to collect blood aspirated from the operating field during surgical procedures and blood from patient's	VT160-C1U 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. VT160-C2U Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U is a

Device	Proposed Devices – Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U Qura S.r.l.	Predicate Device – D101 Kids Sorin Group Italia S.r.l.	Reference Devices – Quantum Perfusion Blood Oxygenator Devices Qura S.r.l.
	diffusion membrane oxygenator, 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 device is limited to 6 hours of use.	veins (gravity or vacuum assisted) during normal operation, to always assure the proper oxygenation capability of the device. The D101 KIDS should not be used longer than 6 hours. Contact with blood for longer periods is not advised. The blood to be treated should contain anticoagulant.	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.
Target population	Adolescent/transitional adolescent (from 12 to 21 years of age)	Infant	Adult
Target User	Perfusionist	Perfusionist	Perfusionist
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	Fiber: polypropylene (PP) Coating: Phosphorylcholine Arterial filter: polyester (PET) Housing: Tritan Sensor: Polycarbonate and silicone-based protective gel
Blood side Connector Type	1/4” (0.635 mm)	1/4” (0.635 mm)	3/8” (9.525 mm)
Max flow rate [l/min] Nominal flow rate [l/min] Min flow rate [l/min]	2.5	2.5	6
Exchange surface [m^2]	0.80	0.61	1.5
Priming Volume [ml]	75	87	145
Single-use	Yes	Yes	Yes
Sterile Condition	EtO Sterile	EtO Sterile	EtO Sterile

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

The following activities were performed to demonstrate product safety and effectiveness requirements and all testing passed by meeting the established requirements set for the use of the devices.

The following data have been provided as requested by FDA in its letter dated August 15, 2023:

- 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:
    - Gas Exchange testing;
    - Mechanical Hemolysis;
    - Leakage testing;
    - Filtration efficiency;
    - Pressure drop testing;
    - Priming volume characterization.

Further this, Qura S.r.l. has updated labeling and Instruction for Use (IFU) according to ISO 15223-1: 2021 Medical Devices – symbols to be used with Medical Device Labels, Labelling and Information to Be Supplied – Part 1: General Requirements [Recognition Nr. 5-134].

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 510(k) submission to support substantial equivalence to legally marketed predicate devices.

VIII. CONCLUSIONS

Based on the Indication for use, technological characteristics, results of non – clinical testing, and comparison to predicate device, Quantum Perfusion Blood Oxygenators have been shown to be substantially equivalent to predicate device Sorin Group Italia S.r.l. Kids D101 (K072091) and reference Qura's own marketed Quantum Perfusion Blood Oxygenator devices (K212341).