January 10, 2022

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

Re: K212688
Trade/Device Name: Quantum PureFlow Standard Heat Exchanger
Quantum PureFlow Cardioplegia Heat Exchanger
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: November 22, 2021
Received: December 10, 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)*
K212688

Device Name
Quantum PureFlow Cardioplegia Heat Exchanger

Indications for Use *(Describe)*
The Quantum PureFlow Cardioplegia Heat Exchanger is intended to be used with a compatible Heater/Cooler system to heat/cool cardioplegic solution, to remove air and to monitor the temperature during routine cardiopulmonary bypass (CPB) procedures up to 6 hours duration. Any blood to be treated must contain anticoagulant. Contact with cardioplegic solution for longer than this period is not permitted. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K212688

Device Name
Quantum PureFlow Standard Heat Exchanger

Indications for Use *(Describe)*
The Quantum PureFlow Standard Heat Exchanger is intended to be used with a compatible Heater/Cooler system to heat/cool blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. 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.

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Section 5.0 510(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
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Date Summary Prepared:	November 22nd, 2021

II. DEVICES

Proprietary Name:	Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger
Common Name:	Standard Heat Exchanger Cardioplegia Heat Exchanger
Classification Name:	Cardiopulmonary bypass heat exchanger
Regulatory Class:	II
Product Code:	DTR
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K212688

III. PREDICATE DEVICES

- Primary Predicate Device for Quantum PureFlow Standard Heat Exchangers

Quantum PureFlow Standard Heat Exchangers are being compared to its primary predicate device:

Trade Name:	Apex Hp M Adult Hollow Fiber Membrane Oxygenator
Registered Establishment Name:	SORIN GROUP ITALIA S.R.L.
Regulation Number:	21 CFR 870.4350
Regulation Name:	Cardiopulmonary bypass oxygenator
Regulatory Class:	II
Product Code:	DTZ
510(k) Number:	K092895

To support other flow variants (Medium and Low Flow) of Quantum PureFlow Standard Heat Exchanger, two reference devices are also being used:

- Sorin Group Italia D101 Kids Infant Hollow Fiber Membrane Oxygenator with integrated Hardshell Cardiotomy/Venous Reservoir

  Trade Name: D101 Kids Infant Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir

  Registered Establishment Name: SORIN GROUP ITALIA S.R.L.

  Regulation Number: 21 CFR 870.4350

  Regulation Name: Cardiopulmonary bypass oxygenator

  Regulatory Class: II

  Product Code: DTZ

  510(k) Number: K072091

- Sorin Group Italia D100 L001 Ph.I.S.I.O D 100 L001 Ph.I.S.I.O Newborn Hollow Fiber Oxygenator with Integrated Hardshell Cardiotomy/Venous Reservoir with phosphorylcholine coating (hereafter D 100 Ph.I.S.I.O)

  Trade Name: D 100 L001 Ph.I.S.I.O: D 100 L001 Ph.I.S.I.O Newborn Hollow Fiber Oxygenator with Integrated Hardshell Cardiotomy Venous Reservoir with phosphorylcholine coating (hereafter referred to as D 100 Ph.I.S.I.O.)

  Registered Establishment Name: SORIN GROUP ITALIA S.R.L.

  Regulation Number: 21 CFR 870.4350

  Regulation Name: Cardiopulmonary bypass oxygenator

  Regulatory Class: II

  Product Code: DTZ

  510(k) Number: K061031

- <u>Predicate Device for Quantum PureFlow Cardioplegia Heat Exchanger (High Flow and Low Flow variants):</u>

  Trade Name: CSC14 Blood Cardioplegia System

  Registered Establishment Name: COBE CARDIOVASCULAR (at time of 510(k) submission, now under SORIN GROUP ITALIA S.R.L. responsibility)

  Regulation Number: 21 CFR 870.4240

  Regulation Name: Cardiopulmonary bypass heat exchanger

  Regulatory Class: Class II

  Product Code: DTR

  510(k) Number: K012898

IV. DEVICE DESCRIPTION

The Qura S.r.l. Quantum PureFlow Heat Exchangers described in this 510(k) are classified in two different product families:

- Quantum PureFlow Standard Heat Exchanger (HX-S);
- Quantum PureFlow Cardioplegia Heat Exchanger (HX-C).

The devices have been designed to manage the temperature of blood (HX-S) or cardioplegic solution and physiological fluids (HX-C) during surgical procedures requiring cardiopulmonary bypass (CPB) for periods lasting less than 6 hours.

HX-S is designed to:

- keep circulating blood at a specific temperature, depending on the type of surgery being performed;
- maintain blood/patient thermoregulation during the CPB;
- rewarm blood at the conclusion of the CPB in order to restore normothermic patient condition.

HX-C is designed to:

- ensure heating/cooling of cardioplegic solution;
- ensure the cardioplegic solution cooling in order to arrest myocardium activity during CPB;
- remove air measure/monitor temperature in the circuit.
- Quantum PureFlow Heat Exchangers (both product families, HX-S and HX-C) described in this 510(k) have been designed to be powered by heater-cooler systems that use water as Heat Transfer Fluid (HTF).

V. INTENDED USE / INDICATIONS FOR USE

- Quantum PureFlow Standard Heat Exchanger:

The Quantum PureFlow Standard Heat Exchanger is intended to be used with a compatible Heater/Cooler system to heat/cool blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. Devices are intended for adult patients.

- Quantum PureFlow Cardioplegia Heat Exchanger:

The Quantum PureFlow Cardioplegia Heat Exchanger is intended to be used with a compatible Heater/Cooler system to heat/cool cardioplegic solution, to remove air and to monitor the temperature during routine cardiopulmonary bypass (CPB) procedures up to 6 hours duration. Any blood to be treated must contain anticoagulant. Contact with cardioplegic solution for longer than this period is not permitted. Devices are intended for adult patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger have the same intended use and operating principle as the predicate and reference devices (Apex Hp M Adult Hollow Fiber Membrane Oxygenator(for HX-S High Flow variant), D101 Kids Infant Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir (reference for HX-S Medium Flow variant), D 100 Ph.I.S.I.O. (reference for HX-S Low Flow variants) and CSC14 Blood Cardioplegia System (for HX-C High and Medium Flow variants), cleared by K092895, K072091, K061031 and K012898, respectively).

In-vitro performance tests have been performed to demonstrate that the proposed devices do not raise any new issues in terms of product's safety or effectiveness as compared to currently cleared predicate products.

Therefore, the Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger can be considered as substantially equivalent to predicate devices, according to FDA's Guidance "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued July 28, 2014.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

The following non-clinical testing was performed to support the substantial equivalence of the Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger 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 Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger devices.

The following data were provided:

- Evaluation of devices' performances:
    - Operating Parameters (priming volume, ease of prime, pressure drop);
    - Air Entrapment (Air handling, Air Handling Through the Purging Port);
    - Mechanical Integrity;
    - Dynamic Blood Damage;
    - Thermal Performance and Compliance;
- Performance evaluation according to ISO 7199:2016 [Recognition Nr. 3-150] (*only for sections applicable to Heat Exchangers);*
- 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 (worst case condition), 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 on Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger have been included in the current Traditional 510(k) submission.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger devices have been shown to be substantially equivalent to legally marketed predicate devices.