



May 6, 2022

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

Re: K220110

Trade/Device Name: Quantum PureFlow Standard Heat Exchanger and 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: April 6, 2022

Received: April 7, 2022

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/pmnmn.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](mailto: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

## Indications for Use

510(k) Number (if known)

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.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## Indications for Use

510(k) Number (if known)

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)

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PRAStaff@fda.hhs.gov

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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: January 12, 2022

### II. DEVICE

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)

### III. PREDICATE 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

#### **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.



Differently from the original submission K212688, 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

or

- Glycol-based solution

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.

No changes have been made to the devices' intended use with respect to the original K212688 submission.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

An additional device model with 3/8" Blood Inlet and Outlet connectors has been introduced in the HX-S product family in order to provide to clinicians/users an additional option to perform the procedure.

New REF code introduced in the portfolio for Quantum PureFlow Standard Heat Exchanger is fully aligned with information provided in original submission K212688 in terms of general structure and materials (including packaging), principle of operation, intended use, manufacturing and sterilization processes. Technical specifications have been verified through testing activities performed according to the same internal applicable standards/protocols of the original cleared devices.

This 510(k) provided testing to demonstrate compatibility with a glycol-based heat transfer fluid (HTF) called CoolFlow DTX. The addition of Glycol-based solution as HTF does not impact devices' design and principle of operation.

Thus, the devices have the same intended use, principle of operation, and technological characteristics. Applicable testing has demonstrated that the proposed devices do not raise any new issues of safety and effectiveness as compared to the currently cleared predicate products.

## **VII. PERFORMANCE DATA**

### **NON-CLINICAL TESTING**

The following activities were performed to demonstrate product safety and effectiveness, considering the proposed change and related impact:

- update of labeling and Instructions for Use (IFU) according to ISO 15223-1:2016 Medical Devices - Symbols to Be Used with Medical Device Labels, Labelling, And Information to Be Supplied - Part 1: General Requirements [Recognition Nr. 5-117];
- Performance tests for new REF code introduced in the portfolio, according to ISO 7199:2016 [Recognition Nr. 3-150] (only for sections applicable to Heat Exchangers).

### **Animal Study**

No animal studies have been performed to support changes object of the present 510(k).





## **CLINICAL TESTING**

No clinical data on Quantum PureFlow Standard Heat Exchanger and Quantum PureFlow Cardioplegia Heat Exchanger have been included in the current 510(k) submission.

## **VIII. CONCLUSIONS**

Considering all changes performed on original devices cleared by K212688, it could be stated that devices under evaluation are identical in terms of intended use and applicable medical technique.

Based on the testing activities, technological characteristics and the indications for use, the proposed have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to Qura's own original devices.