April 13, 2023
Quara S.r.l.
Raffaella Tommasini
QA&RA Director
Via di Mezzo, 23
Mirandola, Modena 41037
Italy

Re: K223879
Trade/Device Name: Quantum PureFlow Standard Heat Exchanger (HX11W-S2, HX11W-S1M and HX11W-S2M)
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary bypass heat exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: March 15, 2023
Received: March 15, 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 (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,
Kathleen M.
Grunder -S
for 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)*
K223879

Device Name
Quantum PureFlow Standard Heat Exchanger (HX11W-S2, HX11W-S1M and HX11W-S2M)

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) procedure 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.***

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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: 23 December, 2022

## II. DEVICE

Proprietary Name: Quantum PureFlow Standard Heat Exchangers (including HX11W-S2, HX11W-S1M and HX11W-S2M, object of present submission)
Common Name: Standard 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 DEVICE

Proprietary Name: Quantum PureFlow Standard Heat Exchangers
Common Name: Standard 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: K220110

## IV. DEVICE DESCRIPTION

The subject of the present Special 510(k) is the Quantum PureFlow Standard Heat Exchanger product family for inclusion of three additional variants with respect to the currently cleared (K220110) portfolio.

Quantum PureFlow Standard Heat Exchanger devices are designed to manage the temperature of blood during surgical procedures requiring cardiopulmonary bypass (CPB) for periods lasting less than 6 hours.

HX-S devices are 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.

Quantum PureFlow Standard Heat Exchangers 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

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.

No changes have been made to the devices' intended use with respect to the original K220110 submission.

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

Additional device models have been introduced in the HX-S product family in order to provide to clinicians/users an additional option to perform cardiopulmonary bypass procedures.

New REF codes introduced in the portfolio for Quantum PureFlow Standard Heat Exchanger product family are aligned with information provided in original submission K220110 in terms of general structure (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.

Applicable testing activities demonstrated that the proposed device model does not raise any new issues of safety and effectiveness as compared to the currently cleared predicate and reference 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 15223-1:2021 Medical Devices - Symbols to Be Used with Medical Device Labels, Labelling, And Information to Be Supplied - Part 1: General Requirements [Recognition Nr. 5-134];
- Performance tests for new REF codes introduced in the portfolio, according to ISO 7199:2016 [Recognition Nr. 3-150].

Animal Study

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

**CLINICAL TESTING**

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

## VIII. CONCLUSIONS

Considering all changes performed on original devices cleared by K220110, 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 devices have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to Qura's own original devices.