November 3, 2021

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

Re: K201320
Trade/Device Name: Quantum PureFlow Centrifugal Blood Pump CP22 with Integrated Sensor
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: October 1, 2021
Received: October 4, 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
Acting 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)*
K201320

Device Name
Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors

Indications for Use *(Describe)*
The Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors indicated for use exclusively with the Quantum Centrifugal Drive of Spectrum Medical is intended to pump the blood through an extracorporeal circuit and to monitor pressure for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

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."

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 – Qura s.r.l.
Phone:	+39 0535 1803050
e-mail:	raffaella.tommasini@quramed.com
Fax:	+39 0535 1803051
Date Summary Prepared:	October 14th, 2020

II. DEVICES

Proprietary Name:	Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
Common Name:	Centrifugal Blood Pump CP22 with Integrated Sensors
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K201320

III. PREDICATE DEVICE

Trade Name:	Quantum PureFlow Centrifugal Blood Pump CP22
Registered Establishment Name:	Qura S.r.l.
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
Panel:	Cardiovascular Devices, Office of Health Technology 2 (OHT2) / Division of Health Technology 2 B (Circulatory Support, Structural and Vascular Devices)
510(k) Number:	K202169

IV. DEVICE DESCRIPTION

The Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors is a standalone single use device intended to pump blood into the extracorporeal circulation circuit and to monitor pressure for periods lasting less than 6 hours. The device is equipped with two sensors integrated in the blood inlet and outlet connectors.

The device is non-toxic, non-pyrogenic, sterilized by ethylene oxide and packaged in a single blister. Blood contact surfaces of the device are coated with a stable biocompatible surface to reduce platelet activation and adhesion while preserving platelet function.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors indicated for use exclusively with the Quantum Centrifugal Drive of Spectrum Medical is intended to pump the blood through an extracorporeal circuit and to monitor pressure for periods lasting less than 6 hours for the purpose of providing either:

i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors has the same intended use, main technological characteristics, and operating principle as the predicate device (Quantum PureFlow Centrifugal Blood Pump CP22, cleared by K202169).

In-vitro performance tests have been performed to support claimed substantial equivalence determining that the proposed device does not raise any new issues in terms of product's safety or effectiveness as compared to the currently cleared predicate device.

The Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors can therefore be considered substantially equivalent to the predicate device according to FDA's Guidance "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued July 28, 2014.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

In-vitro testing was performed to demonstrate the product's substantial equivalence with the predicate device and also to comply with user needs and safety and effectiveness requirements. Testing supplied in the 510(k) Notification includes biocompatibility evaluation, mechanical and performance verification, labeling and Instructions for Use (IFU), 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 21 CFR 870.4360:
    - Operating Parameters;
    - Dynamic Blood Damage;
    - Heat Generation;
    - Air Entrapment;
    - Mechanical Integrity;
    - Durability/Reliability;
- 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.: 14-452];
- 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 device.

VIII. CONCLUSIONS

Based on the indications for use, main technological characteristics and results of non-clinical testing, the Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors device has been demonstrated to be appropriate for its intended use and is considered substantially equivalent to Qura's own marketed predicate device, Quantum PureFlow Centrifugal Blood Pump CP22 (K202169).