October 26, 2023

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

Re: K233091
Trade/Device Name: Quantum Perfusion Centrifugal Blood Pump CP37 with Integrated Sensors
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type blood pump
Regulatory Class: Class II
Product Code: KFM
Dated: September 26, 2023
Received: September 26, 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,

Eric E. Richardson -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233091

Device Name
Quantum Perfusion Centrifugal Blood Pump CP37 with Integrated Sensors

Indications for Use *(Describe)*
The Quantum Perfusion Centrifugal Blood Pump CP37 with Integrated Sensors, indicated for use exclusively with 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 of 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.

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.

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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:	September 26th, 2023

II. DEVICE

Proprietary Name:	Quantum Perfusion Centrifugal Blood Pump CP37 with Integrated Sensors
Common Name:	Centrifugal Blood Pump 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)

III. PREDICATE AND REFERENCE DEVICES

Predicate device:

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

Reference device:

Proprietary Name:	Quantum Perfusion Centrifugal Blood Pump CP37
Common Name:	Centrifugal Blood Pump CP37
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 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 CP37 with Integrated Sensors, indicated for use exclusively with Quantum Centrifugal Drive of Spectrum Medical, are 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.

Devices are intended for adult patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

One additional device model has been introduced in the Centrifugal Blood Pump with Integrated Sensors product family in order to provide to clinicians/users an additional option to perform cardiopulmonary bypass procedures.

New REF code introduced in the portfolio for Quantum Perfusion Centrifugal Blood Pump with Integrated Sensors product family is aligned with information provided in original submission K201320 in terms of general structure (including packaging configuration), 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 issues of safety and effectiveness as compared to the currently cleared predicate and reference product.

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];
- Review and Assessment of data available on predicate(K201320) and reference (K202169) devices submission and applicability to new variant introduced in the product family portfolio.

Animal Study

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

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

Considering all changes performed on original devices cleared K201320 as described in Section “Device Description” of current submission, 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.