September 2, 2020

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

Re: K202169
Trade/Device Name: Quantum PureFlow Centrifugal Blood Pump CP37, Quantum PureFlow Centrifugal Blood Pump CP22
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: July 31, 2020
Received: August 3, 2020

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,

for Fernando Aguel
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)*
K202169

Device Name
Quantum PureFlow Centrifugal Blood Pump CP22

Indications for Use *(Describe)*
The Quantum PureFlow Centrifugal Blood Pump CP22 indicated for use exclusively with the Quantum Centrifugal Drive is intended to pump the blood through an extracorporeal circuit 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."

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)*
K202169

Device Name
Quantum PureFlow Centrifugal Blood Pump CP37

Indications for Use *(Describe)*
The Quantum PureFlow Centrifugal Blood Pump CP37 indicated for use exclusively with the Quantum Centrifugal Drive is intended to pump the blood through an extracorporeal circuit 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)

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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 – Qura s.r.l.
Phone:	+39 0535 1803050
e-mail:	raffaella.tommasini@quramed.com
Fax:	+39 0535 1803051
Date Summary Prepared:	31 July 2020

II. DEVICE

Proprietary Name:	Quantum PureFlow Centrifugal Blood Pump CP22, Quantum PureFlow Centrifugal Blood Pump CP37
Common Name:	Centrifugal Blood Pump
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 DEVICE

Trade Name:	Quantum PureFlow Centrifugal Blood Pump
Registered Establishment Name:	Qura S.r.l.
Regulation Number:	21 CFR §870.4360
Regulation Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
510(k) Clearance:	K192850

IV. DEVICE DESCRIPTION

The Quantum PureFlow Centrifugal Blood Pump CP22/Quantum PureFlow Centrifugal Blood Pump CP37 is a standalone, single use device intended to be used in medical procedures requiring extracorporeal circulation circuits. The pump is designed to move blood by centrifugal force and allow blood flow through the cardiopulmonary bypass or extracorporeal circulation circuits for periods lasting up to 6 hours. The pump is designed to allow the passage of blood through an impeller rotating around its axis.

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.

Within the scope of present Special 510(k) submission, no changes are present related to general structure and components, intended use, available variants and principle of operation; all information contained in original K192850 submission could be considered as still valid.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum PureFlow Centrifugal Blood Pump CP22 indicated for use exclusively with the Quantum Centrifugal Drive is intended to pump the blood through an extracorporeal circuit 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.

The Quantum PureFlow Centrifugal Blood Pump CP37 indicated for use exclusively with the Quantum Centrifugal Drive is intended to pump the blood through an extracorporeal circuit 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

There have been no design changes between the originally cleared device and the proposed device. The only change involves the removal of a warning and a package symbol related to DEHP content from the product labeling.

Thus, the two 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 the subject device is substantially equivalent to the predicate device:

- evaluation of DEHP according to ISO 10993-18 [FDA Recognition Nr. 2-276;
- update of labeling and Instructions for Use (IFU) according to ISO 15223-1:2016 [FDA Recognition Nr. 5-117].

Animal Study

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

CLINICAL TESTING

No clinical testing activities have been performed to support changes object of the present Special 510(k).

VIII. CONCLUSIONS

Considering all changes performed on original devices cleared by K192850, it could be stated that devices under evaluation are identical in terms of intended use, indications for use and applicable medical technique.

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