April 13, 2020

Qura S.r.l.
Raffaella Tommasini
QA&RA Manager
Via di Mezzo, 23
Mirandola, 41037 It

Re: K192850
Trade/Device Name: Quantum PureFlow Centrifugal Blood Pump
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: April 7, 2020
Received: April 9, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192850

Device Name
Quantum PureFlow Centrifugal Blood Pump

Indications for Use *(Describe)*

The Quantum PureFlow Centrifugal Blood Pump 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.

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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 Manager – Qura s.r.l.
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Date Summary Prepared:	April 10, 2020

II. DEVICE

Proprietary Name:	Quantum PureFlow Centrifugal Blood Pump
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

Proprietary Name:	COBE Cardiovascular Revolution Centrifugal Blood Pump with PC Coating (at time of 510(k) submission, now under Sorin Group Italia S.R.L. responsibility, identified as “Revolution Centrifugal Blood Pump”)
Registered Establishment Name:	SORIN GROUP ITALIA S.R.L.
Common Name:	Centrifugal Blood Pump
Classification Name:	Nonroller-type cardiopulmonary bypass blood pump
Regulatory Class:	II
Product Code:	KFM
510(k) Number:	K030462

IV. DEVICE DESCRIPTION

The Quantum PureFlow Centrifugal Blood Pump 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.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum PureFlow Centrifugal Blood Pump 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

The Quantum PureFlow Centrifugal Blood Pump has the same intended use and operating principle as the predicate device (COBE Cardiovascular Revolution Centrifugal Blood Pump with PC Coating, K030462, now under Sorin Group Italia S.R.L. responsibility, identified as “Revolution Centrifugal Blood Pump”).

In-vitro performance tests have been performed in order to support claimed substantial equivalence determining that proposed devices do not raise any new issues in terms of product’s safety or effectiveness if compared to currently cleared predicate products.

Quantum PureFlow Centrifugal Blood Pump can be therefore considered as substantially equivalent to predicate device (COBE Cardiovascular Revolution Centrifugal Blood Pump with PC Coating, K030462), 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 product substantial equivalence with the predicate devices 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 Quantum PureFlow Centrifugal Blood Pump.

The following data were provided:

- Evaluation of devices' performances:
    - Operating Parameters;
    - Dynamic Blood Damage;
    - Heat Generation;
    - Air Entrapment;
    - Mechanical Integrity;
    - Durability/Reliability;
- Evaluation of Hemolysis according to ASTM F1841-97 (Reapproved 2017) [Recognition Nr. 3-56] and ASTM F1830-97 (Reapproved 2017) [Recognition Nr. 3-55];
- Validation of the EtO Sterilization process, according to ISO 11135:2014 [Recognition Nr.: 14-452],
- Packaging Validation tests according to ISO 11607-1:2019 [Previous Edition Recognition Nr. 14-454];
- Biocompatibility of the finished product (worst case condition), 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 on the Quantum PureFlow Centrifugal Blood Pump have been included in the current Traditional 510(k) submission.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to the predicate device, the Quantum PureFlow Centrifugal Blood Pump has been shown to be substantially equivalent to a legally marketed predicate device.