May 19, 2023

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

Re: K220842
Trade/Device Name: Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors, Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type blood pump
Regulatory Class: Class II
Product Code: KFM
Dated: April 13, 2023
Received: April 14, 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

Kathleen Grunder
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)*
K220842

Device Name
Quantum Perfusion Centrifugal Blood Pump CP20

Indications for Use *(Describe)*
The Quantum Perfusion Centrifugal Blood Pump CP20, indicated for use exclusively with Quantum Centrifugal Drive of Spectrum Medical, 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

Device is intended for adolescent patients (i.e., patients greater than 12 through 21 years of age)

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

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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)*
K220842

Device Name
Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors

Indications for Use *(Describe)*
The Quantum Perfusion Centrifugal Blood Pump CP20 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 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.

Device is intended for adolescent patients (i.e., patients greater than 12 through 21 years of age)

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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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:	April the 13th, 2023

II. DEVICE

Proprietary Name:	Quantum Perfusion Centrifugal Blood Pump CP20 Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors
Common Name:	Centrifugal Blood Pump CP20 Centrifugal Blood Pump CP20 with Integrated Sensors and
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
Panel:	Cardiovascular Medical Specialty 74 - 21 CFR Part 870 Office of Product Evaluation and Quality / Office of Health Technology 2 (OHT2 Cardiovascular Devices) / Division of Health Technology 2B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE AND REFERENCE DEVICES

Predicate device:

Trade Name:	Levitronix PediMag Blood Pump
Registered Establishment Name:	LEVITRONIX LLC (now Thoratec Switzerland GMBH)
Common Name:	PediMag Blood Pump
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
510(k) Number:	K090051

Reference device:

Trade Name:	Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
Registered Establishment Name:	Qura S.r.l.
Common Name:	Centrifugal Blood Pump CP22 with Integrated Sensors
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class:	II
Product Code:	KFM
510(k) Clearance:	K201320

IV. DEVICE DESCRIPTION

Quantum Perfusion Centrifugal Blood Pump CP20 and Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors are standalone single use device intended to pump blood into the extracorporeal circulation circuit and to monitor pressure for periods lasting less than 6 hours.

Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors is equipped with two sensors integrated in the blood inlet and outlet connectors.

Devices are 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

Quantum Perfusion Centrifugal Blood Pump CP20

The Quantum Perfusion Centrifugal Blood Pump CP20, indicated for use exclusively with Quantum Centrifugal Drive of Spectrum Medical, is intended to pump the blood through an extracorporeal circuit for periods up to 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

Device is intended for adolescent patients (i.e. patients greater than 12 through 21 years of age).

Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors

The Quantum Perfusion Centrifugal Blood Pump CP20 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 up to 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.

Device is intended for adolescent patients (i.e. patients greater than 12 through 21 years of age).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICE

A comparison between Quantum Perfusion Centrifugal Blood Pump CP20 and Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors and the predicate/reference devices has been conducted and provided in the following table.

Device	Proposed Devices Quantum Perfusion Centrifugal Blood Pump CP20 Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors	Predicate Device – Levitronix PediMag Blood Pump	Reference Device – Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
Name	Quantum Perfusion Centrifugal Blood Pump CP20 Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors	Levitronix PediMag Blood Pump	Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
510(k) Number	K220842	K090051	K201320
Device description	Devices have been designed to pump blood into the extracorporeal circulation circuit. Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors is equipped with two sensors positioned on the blood inlet and outlet connectors. Both sensors are able to measure the pressure at the same time. All the device surfaces in contact with blood are treated with a phosphorylcholine-based biocompatible coating. Contact with blood for a period of more than 6 hours is not allowed.	The PediMag Blood Pump is a sterile, single-use, disposable, non-coated, polycarbonate centrifugal blood pump. The pump has a 14 ml priming volume. The pump inlet is on the rotational axis of the impeller whereas the pump outlet is perpendicular to the inlet and tangent to the outer diameter. Both the inlet and outlet ports include standard 1/4 inch barbed connectors for easy mating to standard medical grade 1/4 inch tubing. The Pump is designed to move blood by centrifugal force created by the magnetically suspended rotating impeller.	The device has been designed to pump blood into the extracorporeal circulation circuit. The device is equipped with two sensors positioned on the blood inlet and outlet connectors. Both sensors are able to measure the pressure at the same time. All the device surfaces in contact with blood are treated with a phosphorylcholine-based biocompatible coating. Contact with blood for a period of more than 6 hours is not allowed.
Regulation #	21 CFR §870.4360	21 CFR §870.4360	21 CFR §870.4360

Device	Proposed Devices Quantum Perfusion Centrifugal Blood Pump CP20 Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors	Predicate Device – Levitronix PediMag Blood Pump	Reference Device – Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
Regulation Name	Nonroller-type cardiopulmonary bypass blood pump	Nonroller-type cardiopulmonary bypass blood pump	Nonroller-type cardiopulmonary bypass blood pump
Product Code	KFM	KFM	KFM
Classification	II	II	II
Indication for Use	<u>Quantum Perfusion Centrifugal Blood Pump CP20</u> The Quantum Perfusion Centrifugal Blood Pump CP20, indicated for use exclusively with Quantum Centrifugal Drive of Spectrum Medical, is intended to pump the blood through an extracorporeal circuit for periods up to 6 hours for the purpose of providing either: (iii) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (iv) 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. Device is intended for adolescent patients (i.e. patients greater than 12 through 21 years of age). <u>Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors</u> The Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors,	The PediMag Blood Pump is indicated for use with the CentriMag Circulatory Support System console and motor to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as mitral valve reoperation. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.). The PediMag Pump can generate a maximum pump flow equal to 1.5 liters per minute, limiting its use to pediatric patients. The PediMag Blood Pump is indicated for use only with the CentriMag	The Quantum Perfusion Centrifugal Blood Pump 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 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.

Device	Proposed Devices Quantum Perfusion Centrifugal Blood Pump CP20 Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors	Predicate Device – Levitronix PediMag Blood Pump	Reference Device – Quantum Perfusion Centrifugal Blood Pump CP22 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 up to 6 hours for the purpose of providing either: (iii) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (iv) 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. Device is intended for adolescent patients (i.e., patients greater than 12 through 21 years of age).	Console and Motor.	
Target population	Adolescent patients (i.e. patients greater than 12 through 21 years of age)	Pediatric population	Adult population
Target User	Perfusionist	Perfusionist	Perfusionist
Main Contacting Materials	Polycarbonate Coating: Phosphorylcholine Variant with integrated sensor: Sensor made with polycarbonate and silicone-based protective gel	Polycarbonate	Polycarbonate Coating: Phosphorylcholine Sensor: polycarbonate and silicone-based protective gel
Priming Volume	20 ml	14 ml	22 ml

Device	Proposed Devices Quantum Perfusion Centrifugal Blood Pump CP20 Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors	Predicate Device – Levitronix PediMag Blood Pump	Reference Device – Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors
Maximum Blood Flow Rate	1.5 l/min	1.5 l/min	7 l/min
Maximum Pump Operating Pressure	550 mmHg	540 mmHg	550 mmHg
Presence of sensors	Yes (Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors only)	No	Yes
Single-use	Yes	Yes	Yes
Sterile Condition	EtO Sterile	EtO Sterile	EtO Sterile

Table. 5-1 – Comparative Data

Based on the indications for use, main technological characteristics and results of non-clinical testing, subject device has been demonstrated to be appropriate for its intended use and is considered substantially equivalent to legally marketed predicate and reference device according to FDA's Guidance "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued July 28, 2014.

Furthermore, *in-vitro* performance tests have been performed to demonstrate that the proposed device does not raise any new issues in terms of product's safety or effectiveness as compared to predicate device.

VII. PERFORMANCE DATA

NON-CLINICAL TESTING

In-vitro testing was performed to comply with user needs and safety and effectiveness requirements and demonstrate substantial equivalence with the predicate and reference devices with reference to FDA's document "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s" and defined applicable standards for the products.

The following areas have been tested and/or evaluated:

- Performance tests, according to applicable special controls according to 21 CFR 870.4360 and ISO 18242 [Recognition Nr. 3-163].

Tests are mainly related to:

  - Operating Parameters;
  - Dynamic Blood Damage;
  - Heat Generation;
  - Air Entrapment;
  - Mechanical Integrity;
  - Durability/Reliability;

- Evaluation of product shelf life;
- Validation of the EtO Sterilization process, according to ISO 11135 [Recognition Nr.: 14-529],
- Packaging Validation tests, according to according to ISO 11607-1 [Recognition Nr. 14-530],
- Biocompatibility of the finished product, according to 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 and reference devices.

VIII. CONCLUSIONS

Based on the indications for use, main technological characteristics and results of non-clinical testing, the Quantum Perfusion Centrifugal Blood Pump CP20 and Quantum Perfusion Centrifugal Blood Pump CP20 with Integrated Sensors devices have been demonstrated to be appropriate for the intended use and are considered substantially equivalent to predicate device, Levitronix PediMag Blood Pump (K090051) and reference Qura’s own marketed Quantum Perfusion Centrifugal Blood Pump CP22 with Integrated Sensors (K201320).