April 13, 2020

Spectrum Medical Ltd
Colleen Powell
Director of Regulatory Affairs
Harrier 4, Meteor Business Park, Cheltenham Road East
Gloucester, GL2 9QL Gb

Re: K192838
Trade/Device Name: Quantum Centrifugal Drive
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA
Dated: April 8, 2020
Received: April 9, 2020

Dear Colleen Powell:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192838

Device Name
Quantum Centrifugal Drive

Indications for Use *(Describe)*
The Quantum Centrifugal Drive is a cardiopulmonary bypass speed control device indicated for use for exclusively with the Quantum PureFlow Centrifugal Blood Pump for speed-controlled pumping through the extracorporeal circuit for typical durations of six hours or less.

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.

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510(k) Summary

I. SUBMITTER

Name:	Spectrum Medical Ltd
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Contact Person:	Colleen Powell, Director of Regulatory Affairs
Phone:	+44 (0) 1242 650 120
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Date Summary Prepared:	October 2, 2019

II. DEVICE

Proprietary Name:	Quantum Centrifugal Drive
Common Name:	Cardiopulmonary bypass pump speed control
Classification Name:	Control, Pump Speed, Cardiopulmonary Bypass
Regulatory Class:	II
Product Code:	DWA
Panel:	Office of Health Technology 2 (OHT2 Cardiovascular Devices) / Division of Health Technology 2B (Circulatory Support, Structural and Vascular Devices)

III. PREDICATE DEVICE

The predicate device for this submission is the Sorin/LivaNova Stöckert Centrifugal Pump (K011838).

IV. DEVICE DESCRIPTION

The Quantum Centrifugal Drive is a cardiopulmonary speed control device intended to be used for pumping arterial blood through the cardiopulmonary bypass circuit. The Quantum Centrifugal Drive is available in two models – High Pressure and Low Pressure.

The Quantum Centrifugal Drive is designed to work with the Quantum Pump Manager software application, as part of the Quantum Pump Console (K173834). The Quantum Centrifugal Drive is magnetically coupled exclusively with Quantum Pureflow Centrifugal Blood Pumps, designed and manufactured by Qura s.r.l. The operation of the Quantum Centrifugal Drive is managed from the Quantum Workstation (K163657).

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Centrifugal Drive is a cardiopulmonary bypass speed control device indicated for use for exclusively with the Quantum PureFlow Centrifugal Blood Pump for speed-controlled pumping through the extracorporeal circuit for typical durations of six hours or less.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Spectrum Medical Ltd.'s Quantum Centrifugal Drive and Sorin/LivaNova's Stöckert Centrifugal Pump have the same intended use, indications for use, clinical setting, target user, target patient population, and principle of operation. Both devices magnetically couple to a disposable centrifugal pump head.

However, the Quantum Centrifugal Drive has two different models and can generate a higher number of revolutions per minute (RPM) compared to the predicate device. The Quantum Centrifugal Drive can also be controlled from the touchscreen interface on the Quantum Workstation or by using rotating knobs on the Quantum Pump Control Module. While both devices contain safety features to protect against low RPMs, this protection is automatically controlled by software on the Quantum Centrifugal Drive.

These differences in technological characteristics do not raise new issues of safety or effectiveness.

VII. PERFORMANCE DATA – NON-CLINICAL TESTING

No animal testing was submitted to support the substantial equivalence of the Quantum Centrifugal Drive to the Sorin/LivaNova Stöckert Centrifugal Pump. The following non-clinical testing was performed to support the substantial equivalence of the Quantum Centrifugal Drive to the legally marketed predicate:

- Electrical safety
- Electromagnetic compatibility (EMC)
- Electrosurgery interference
- Hardware testing
- Software verification and validation

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the Quantum Centrifugal Drive to the Sorin/LivaNova Stöckert Centrifugal Pump.

IX. CONCLUSIONS

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