May 25, 2018

Spectrum Medical Ltd
Mark Drain
Chief Financial Officer
Harrier 4, Meteor Business Park, Cheltenham Road East
Gloucester, GL2 9QL GB

Re: K173834
Trade/Device Name: Quantum Pump Console
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ
Dated: April 24, 2018
Received: April 25, 2018

Dear Mark Drain:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K173834

Device Name
Quantum Pump Console

Indications for Use *(Describe)*
The Quantum Pump Console is indicated for use for up to 6 hours in cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

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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I. SUBMITTER

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Contact Person: Mr. Mark Drain, Chief Financial Officer

Date Summary Prepared: December 15, 2017

II. DEVICE

Proprietary Name:	Quantum Pump Console
Common Name:	Heart-Lung Machine
Classification Name:	Console, Heart-Lung Machine, Cardiopulmonary Bypass (21 CFR 870.4220)
Regulatory Class:	II
Product Code:	DTQ
Panel:	Office of Device Evaluation (ODE) / Division of Cardiovascular Devices (DCD) Circulatory Support Devices Branch (CSDB)

III. PREDICATE DEVICE

Stöckert S5 System (K060053) currently marketed by LivaNova

IV. DEVICE DESCRIPTION

The Quantum Pump Console is a configurable heart-lung machine consisting of various components controlled by a central workstation. The system is intended to be used in any surgery in which the patient's blood is being oxygenated extracorporeally. The modular system consists of a frame, power supply with battery backup, roller pumps, pump control module, diagnostic module and a central workstation with the user interface.

The roller pumps are available in three sizes (4”, 6” and 8”) and can be controlled via a centralized interface on the Quantum Workstation touchscreen or through the Quantum Pump Console, which contains five knobs and displays in one integrated console.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Pump Console is indicated for use for up to 6 hours in cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Spectrum Medical Ltd’s Quantum Pump Console and LivaNova’s S5 System have the same intended use/indications for use, clinical setting, target user, target patient population, principle of operation for the pumps and same pump speed and accuracy.

Whereas the S5 System uses multiple screens for its interface and each pump has an individual screen, the Quantum Pump Console uses a single, centralized touchscreen interface. The S5 System can only control the pumps with a rotating knob on each pump while the Quantum Pump Console can control the pumps with its centralized user interface or with rotating knobs on a single integrated pump control module.

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 Pump Console to the S5 System. The following non-clinical testing was performed to support the substantial equivalence of the Quantum Pump Console to the S5 System:

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

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the Quantum Pump Console to the S5 System.

IX. CONCLUSIONS

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