May 24, 2019

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

Re: K190282
Trade/Device Name: Quantum Smart Occluder
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ
Dated: February 8, 2019
Received: February 11, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for Nicole Ibrahim
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)*

K190282

Device Name
Quantum Smart Occluder

Indications for Use *(Describe)*

The Quantum Smart Occluder is indicated for use as an accessory with the Quantum Pump Console for up to 6 hours in the extracorporeal circulation of blood for 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: Colleen Powell, Director of Regulatory Affairs

Date Summary Prepared: February 6, 2019

II. DEVICE

Proprietary Name:	Quantum Smart Occluder
Common Name:	Electronic Tube Clamp
Classification Name:	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

The Quantum Smart Occluder is an accessory to the Quantum Pump Console. The predicate devices for this submission are listed below:

(Primary) - Sorin/LivaNova Stockert S5 System (K060053);

(Reference) - Quantum Pump Console (K173834).

(Reference) - Quantum Diagnostic Module (K173591)

These predicates will be used to determine substantial equivalence.

IV. DEVICE DESCRIPTION

The Quantum Smart Occluder is a clamping system for the occlusion of both arterial and venous blood lines. The Quantum Smart Occluder is designed to work with the Quantum Pump Manager software application, as part of the Quantum Pump Console (K173834). The operation of the Quantum Smart Occluder is managed from the Quantum Workstation (K163657).

The Quantum Smart Occluder has the availability for 5 sensor attachments:

- 2 Flow Sensors
- 2 Pressure Sensors
- 1 Level Sensor

These sensors are identical with the use of the same sensor PCB boards previously cleared with the Quantum Diagnostic Module (K173591) and Quantum Ventilation Module (K181942). These sensor connections can be used in conjunction with the sensor connections used on the Quantum Diagnostic Module (K173591) or Quantum Ventilation Module (K181942) to provide additional readings. Or used solely on the Quantum Smart Occluder to reduce the amount of cabling that is attached to the Quantum Pump Console (K173834).

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Smart Occluder is indicated for use as an accessory with the Quantum Pump Console for up to 6 hours in the extracorporeal circulation of blood for 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 Smart Occluder, Sorin/LivaNova Stockert S5 System (K060053), the Quantum Pump Console (K173834) and the Quantum Diagnostic Module (K173591) have the same intended use/indications for use, clinical setting, target user, target patient population, principle of operation. The Quantum Smart Occluder, Sorin/LivaNova Stockert S5 System and the Quantum Diagnostic Module provide measurements via attached sensors for blood flow, bubble detection, pressure and level. For the Quantum Smart Occluder and Quantum Diagnostic Module, the sensors and sensor PCB boards are identical. The Quantum Smart Occluder, Quantum Diagnostic Module and Quantum Pump Console (K173834) are controlled from the Quantum Workstation.

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 Smart Occluder to the predicate devices. The following non-clinical testing was performed to support the substantial equivalence of the Quantum Smart Occluder to the named predicate devices:

- 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 Smart Occluder to the predicate devices.

IX. CONCLUSIONS

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