May 4, 2021

Spectrum Medical Ltd.
Colleen Powell
Director, Regulatory Affairs
Harrier 4, Meteor Business Park, Cheltenham Road East
Gloucestershire, Gloucester GL29QL
United Kingdom

Re: K210669
Trade/Device Name: Quantum Mini Ventilation Module
Regulation Number: 21 CFR 870.4300
Regulation Name: Cardiopulmonary Bypass Gas Control Unit
Regulatory Class: Class II
Product Code: DTX
Dated: March 4, 2021
Received: March 5, 2021

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,

Nicole Gillette
Assistant Director (Acting)
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 March 4, 2021
See PRA Statement below.

510(k) Number *(if known)*

K210669

Device Name
Quantum Mini Ventilation Module

Indications for Use *(Describe)*

The Quantum Mini Ventilation Module is intended to provide independently regulated O2 outputs for a controlled flow of O2 into the ECC circuit. The Quantum Mini Ventilation Module is an accessory that works with the Quantum workstation.

The following parameters are provided by the Quantum Mini Ventilation Module:
• Control of gas flow (O2)
• Extracorporeal gas flow measurements for O2

The Quantum Mini Ventilation Module is only to be used by an experienced and trained clinician. It is not intended to be used by a patient or other untrained personnel.

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 387082
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Date Summary Prepared:	March 4, 2021

II. DEVICE

Proprietary Name:	Quantum Mini Ventilation Module
Common Name:	Gas control unit for heart lung machine
Classification Name:	Gas Control Unit, Cardiopulmonary Bypass (21 CFR 870.4330)
Regulatory Class:	II
Product Code:	DTX
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 Spectrum Medical Ltd.'s Quantum Ventilation Module (K202733).

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Quantum Mini Ventilation Module is a gas control unit that is intended to provide independently regulated oxygen outputs for a controlled flow for procedures involving an extracorporeal circuit.

The Quantum Mini Ventilation Module provides a simplified patient ventilation capability. The device consists of a single O_2 input port that receives oxygen from the hospital infrastructure and two (2) oxygen outputs that are designed to provide O_2 sweep and pO_2 Reg.

The device interfaces with and is powered by any model of the Quantum workstation. The Quantum Mini Ventilation Module does not contain any user interface; instead, all measurements are displayed on the Quantum workstation.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Mini Ventilation Module is intended to provide independently regulated O_2 outputs for a controlled flow of O_2 into the ECC circuit. The Quantum Mini Ventilation Module is an accessory that works with the Quantum workstation.

The following parameters are provided by the Quantum Mini Ventilation Module:

- Control of gas flow (O_2)
- Extracorporeal gas flow measurements for O_2

The Quantum Mini Ventilation Module is only to be used by an experienced and trained clinician. It is not intended to be used by a patient or other untrained personnel.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Quantum Mini Ventilation Module and cleared Quantum Ventilation Module have the same intended use as both are designed to monitor parameters in extracorporeal circuits and provide gas delivery to the oxygenator. Both devices have the same manufacturer, clinical application, clinical setting, target user and target patient population. Both devices are powered by and display measurements on the Quantum workstation. Both devices are part of the gas line to the oxygenator in an extracorporeal circuit and can measure oxygen flow.

However, the proposed Quantum Mini Ventilation Module only has one gas supply (oxygen) compared to three gas supplies with the cleared device. The proposed device does not have vacuum management functionality and cannot provide any physiological measurements like the cleared Quantum Ventilation Module. Furthermore, the proposed device does not have a display and can only be controlled by the Quantum workstation, while the predicate device has rotary knobs and touchscreen display which can be used for control.

The proposed Quantum Mini Ventilation Module is substantially equivalent with regards to intended use, technology, and performance specifications to the currently cleared Quantum Ventilation Module. The differences between the devices 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 Mini Ventilation Module to the Quantum Ventilation Module (QVM2).

The following non-clinical testing was performed to support the substantial equivalence of the Quantum Mini Ventilation Module to the legally marketed predicate device:

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

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the Quantum Mini Ventilation Module to the Quantum Ventilation Module.

IX. CONCLUSIONS

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