October 16, 2020

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

Re: K202733
Trade/Device Name: Quantum Ventilation Module
Regulation Number: 21 CFR 870.4300
Regulation Name: Cardiopulmonary Bypass Gas Control Unit
Regulatory Class: Class II
Product Code: DTX
Dated: September 17, 2020
Received: September 18, 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,

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202733

Device Name
Quantum Ventilation Module

Indications for Use *(Describe)*
The Quantum Ventilation Module is intended for the continuous monitoring of critical clinical parameters during procedures that require extracorporeal circulation. The Quantum Ventilation Module is an accessory that only works with the Quantum Workstation. Parameters provided by the Quantum Ventilation Module include:

- Measurement of up to three blood flow channels and arterial and venous flow differential and gas bubbles
- Extracorporeal gas flow measurements that includes O2 & CO2 and calculated CO2 removal
- Predicted PO2 and PCO2
- Up to three temperature channels
- Up to three circuit pressure channels
- Reservoir level indication
- Two channels of vacuum
- Blend and control gas flow (air/O2/CO2)

The Quantum Ventilation Module is to only be used by an experienced and trained clinician. The device is not intended to be used by the 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
Fax:	+44 (0) 8452 808 127
Date Summary Prepared:	September 17, 2020

II. DEVICE

Proprietary Name:	Quantum Ventilation Module
Common Name:	Gas blender for heart lung machine
Classification Name:	Gas Control Unit, Cardiopulmonary Bypass (21 CFR 870.4300)
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 (K181942).

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

IV. DEVICE DESCRIPTION

The Quantum Ventilation Module is an on-line, cardiopulmonary bypass, blood gas monitor that is used for extracorporeal monitoring of blood oxygen (arterial and venous) saturation, hematocrit, and hemoglobin levels. The Quantum Ventilation Module provides gas blending and continuous non-invasive monitoring of critical clinical parameters in extracorporeal circuits used in cardiopulmonary bypass (CPB) or extracorporeal membrane oxygenation (ECMO) procedures. The Quantum Ventilation Module is an accessory to the Quantum Workstation. When paired with the Quantum Workstation, the combination of the Quantum Workstation and Quantum Ventilation Module (QVM2) is known as the Quantum Ventilation System.

The Quantum Ventilation Module performs five functions:

1. Provides measurements from embedded and attached sensors to monitor gases into and out of a blood oxygenator.

2. Provides measurements from attached sensors for blood flow, bubble detection, pressure, level, and temperature to monitor an extracorporeal blood loop.
3. Provides gas blending to ensure the precision delivery of FiO_2, CO_2 and sweep flow rates.
4. Provides regulation of vacuum supply to provide two channels of vacuum.
5. Sends these physiological measurements to the Quantum Workstation for display to the user.

The Quantum Ventilation Module, with its attached sensors, can measure flow, pressure, reservoir level, temperature and gas diagnostics, in addition to performing electronic gas blending of up to three gases and built-in vacuum management for the removal of waste anesthetic gas. The primary interface for controlling and displaying measurements is the Quantum Workstation; however, the Quantum Ventilation Module also contains a touchscreen display with control knobs. The Quantum Ventilation Module only works with the Quantum Workstation.

V. INTENDED USE / INDICATIONS FOR USE

The Quantum Ventilation Module is intended for the continuous monitoring of critical clinical parameters during procedures that require extracorporeal circulation. The Quantum Ventilation Module is an accessory that only works with the Quantum Workstation. Parameters provided by the Quantum Ventilation Module include:

- Measurement of up to three blood flow channels and arterial and venous flow differential and gas bubbles
- Extracorporeal gas flow measurements that includes O2 & CO2 and calculated CO2 removal
- Predicted PO2 and PCO2
- Up to three temperature channels
- Up to three circuit pressure channels
- Reservoir level indication
- Two channels of vacuum
- Blend and control gas flow (air/O2/CO2)

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The cleared Quantum Ventilation Module (QVM) and proposed Quantum Ventilation Module (QVM2) have the same intended use as both are designed to monitor critical parameters in extracorporeal circuits. Both devices have the same clinical application, clinical setting, target user and target patient population and are powered from another device via cable. Both devices also have the same manufacturer, same diagnostic measurements, equivalent sensor performance and same principle of operation of its sensors.

Both Quantum Ventilation Modules blend gas electronically and can blend air, oxygen, and carbon dioxide (air/O2/CO2). Both devices are part of the gas line to the oxygenator in an extracorporeal circuit and has two vacuum channels. Diagnostic measurements of blood flow, bubble detection, circuit pressure, blood reservoir level, and temperature can be made by both devices.

The proposed Quantum Ventilation Module has added a second vacuum supply wall port, in addition to an optional sample line for extracted gas analysis. Improvements to the user interface, including enhanced touchscreen capability, have been added to the modified device.

The proposed Quantum 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 Ventilation Module (QVM) to the Quantum Ventilation Module (QVM2).

The following non-clinical testing was performed to support the substantial equivalence of the Quantum Ventilation Module (QVM2) 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 Ventilation Module (QVM2) to the Quantum Ventilation Module (QVM).

IX. CONCLUSIONS

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Quantum Ventilation Module (QVM2) has been shown to be substantially equivalent to a legally marketed predicate device.