October 2, 2020

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

Re: K202557
Trade/Device Name: Quantum Workstation 12" Elite
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary Bypass On-Line Blood Gas Monitor
Regulatory Class: Class II
Product Code: DRY
Dated: September 1, 2020
Received: September 3, 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)*

K202557

Device Name

Quantum Workstation 12" Elite

Indications for Use *(Describe)*

The intended use of the Quantum Workstation 12" Elite is for the non-invasive continuous monitoring of oxygen saturation and hematocrit / hemoglobin concentration of the blood and in an extracorporeal circuit. When using its range of accessories, the Quantum Workstation 12" Elite is configured to measure and display the following measurements:

- SaO2 Arterial Saturation (%)
- SvO2 Venous Saturation (%)
- Hb Hemoglobin (g/L and gm/dl)
- Hct Calculated Hematocrit (%)
- Blood Flow - 2 channels with arterial and venous flow differentials
- Pressure & Temperature - 4 channels

The Quantum Workstation 12" Elite provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

The workstation's monitoring and alarm functionality does not directly control patient care. The User makes clinical judgments regarding the treatment of the patient as a result of information displayed by the workstation.

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:	September 1, 2020

II. DEVICE

Proprietary Name:	Quantum Workstation 12” Elite
Common Name:	Blood Gas Monitor
Classification Name:	Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass (21 CFR 870.4330)
Regulatory Class:	II
Product Code:	DRY
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 Workstation 12.1” (K181923). This predicate has not been subject to a design-related recall. Three reference devices manufactured by Spectrum Medical Ltd. were used, and these included the Quantum Diagnostic Module (K173591), Quantum Smart Occluders (K190282) and Quantum Pump Console (K173834).

IV. DEVICE DESCRIPTION

The Quantum Workstation 12” Elite 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 device’s enhanced functionality includes the ability to control centrifugal or roller pumps and make blood flow, blood pressure and blood temperature measurements.

The Quantum Workstation 12” Elite consists of a pole-mounted 12.1” landscape high definition touch screen. The touch screen displays individual and trend readings with alarm settings. The Quantum Workstation 12” Elite provides memory storage via an SD (Secure Digital) card. The Quantum Workstation 12” Elite is powered from the AC Mains supply and incorporates a battery

backup that automatically switches on in the event of an interruption to the mains power supply. The battery backup is provided via two (2) lithium-ion batteries with a two-hour minimum life.

The Quantum Workstation 12" Elite includes the following ports / connections:

- One (1) sensor port for the Hb / SO_2 sensor
- Two (2) sensor ports for blood flow
- Two (2) sensor ports for blood pressure/temperature
- One (1) LAN / Ethernet port
- Two (2) USB 2.0 ports
- Three (3) Spectrum Medical ports
- One (1) User Serial Port

Accessories for the Quantum Workstation 12" Elite include the power supply, mounting arm (long or short), Hb / SO_2 sensor, flow sensors and pressure/temperature sensors.

V. INTENDED USE / INDICATIONS FOR USE

The intended use of the Quantum Workstation 12" Elite is for the non-invasive continuous monitoring of oxygen saturation and hematocrit / hemoglobin concentration of the blood in an extracorporeal circuit. When using its range of accessories, the Quantum Workstation 12" Elite is configured to measure and display the following measurements:

SaO_2	Arterial Saturation (%)
SvO_2	Venous Saturation (%)
Hb	Hemoglobin (g/L, gm/dl and mmol/L)
Hct	Calculated Hematocrit (%)
Blood Flow	2 channels with arterial and venous flow differentials
Pressure and temperature	4 channels

The Quantum Workstation 12" Elite provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

The workstation's monitoring and alarm functionality does not directly control patient care. The User makes clinical judgments regarding the treatment of the patient as a result of information displayed by the workstation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Spectrum Medical Ltd's Quantum Workstation 12.1" (K181923) and Quantum Workstation 12" Elite have the same manufacturer, intended use, clinical application, clinical setting / site of use, target user, target patient population, and principle of operation / mechanism of operation / fundamental scientific technology. They also have the same performance for SO_2, Hb, and Hct. They both have an Ethernet port and SD card memory storage. They both are also compatible with the intended environment and with other devices.

Spectrum Medical Ltd's Quantum Workstation 12" Elite and Quantum Workstation 12.1" differ in

that the Quantum Workstation 12” Elite provides additional measurements for blood flow, pressure and bubble detection. The Quantum Workstation 12” Elite can also control centrifugal or roller pumps.

These differences 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 Workstation 12” Elite to the Quantum Workstation 12.1”.

The following non-clinical testing was performed to support the substantial equivalence of the Quantum Workstation 12” Elite 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 Workstation 12” Elite to the Quantum Workstation 12.1”.

IX. CONCLUSIONS

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Quantum Workstation 12” Elite has been shown to be substantially equivalent to a legally marketed predicate device.