August 17, 2018

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

Re: K181923
Trade/Device Name: Quantum Workstation 12.1"
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor
Regulatory Class: Class II
Product Code: DRY
Dated: July 13, 2018
Received: July 18, 2018

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,

Fernando Aguel -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181923

Device Name
Quantum Workstation 12.1"

Indications for Use *(Describe)*

The intended use of the Quantum Workstation 12.1" is for the non-invasive continuous monitoring of oxygen saturation and haemotocrit / haemoglobin concentration of the blood in an extracorporeal circuit. When using its range of accessories, the Quantum Workstation 12.1" is configured to measure and display the following measurements:

SaO2 Arterial Saturation (%)
SvO2 Venous Saturation (%)
Hb Haemogloblin (g/L and gm/dl and mmol/l)
Hct Calculated Haematocrit (%)

The Workstation 12.1" provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

The Workstation 12.1"'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 12.1".

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

I. SUBMITTER

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Contact Person: Mrs. Colleen Powell, Director of Regulatory Affairs

Date Summary Prepared:

II. DEVICE

Proprietary Name:	Quantum Workstation 12.1"
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 Device Evaluation (ODE) / Division of Cardiovascular Devices (DCD) Circulatory Support Devices Branch (CSDB)

III. PREDICATE DEVICE

Spectrum Medical Ltd's Quantum Workstation (K163657)

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

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Quantum Workstation 12.1" is an online, cardiopulmonary bypass, blood gas monitor. It is used for extracorporeal monitoring of blood oxygen (arterial and venous) saturation, hematocrit, and hemoglobin levels.

The Quantum Workstation 12.1" 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 12.1" has a Wi-Fi adapter and provides memory storage via an SD (Secure Digital) card. The Quantum Workstation 12.1" is powered from the AC Mains supply and also 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 12.1" includes the following ports / connections:

- One (1) sensor port for the Hb / SO_2 sensor
- One (1) LAN / Ethernet port
- Three (3) USB 2.0 ports
- Eight (8) additional LAN ports – described as SAP (Spectrum Accessory Ports) to support a range of Spectrum Medical manufactured modules – these are for future use

Accessories for the Quantum Workstation 12.1" include the power supply, mounting arm (long or short), and Hb / SO_2 sensor. Different Hb / SO_2 sensors are available based on the diameter and thickness of the extracorporeal tubing.

V. INTENDED USE / INDICATIONS FOR USE

The intended use of the Quantum Workstation 12.1" is for the non-invasive continuous monitoring of oxygen saturation and haematocrit / haemoglobin concentration of the blood in an extracorporeal circuit. When using its range of accessories, the Quantum Workstation 12.1" is configured to measure and display the following measurements:

SaO_2	Arterial Saturation (%)
SvO_2	Venous Saturation (%)
Hb	Haemoglobin (g/L and gm/dl)
Hct	Calculated Haematocrit (%)

The Workstation 12.1" provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

The Workstation 12.1"'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

As shown in **Table A**, Spectrum Medical Ltd's Quantum Workstation (K163657) and Quantum Workstation 12.1" 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 display individual and trend readings with alarm settings and don't require recalibration due to negligible drift. They both have a Wi-Fi adapter, Ethernet port, and SD card memory storage. They both run on line power with battery backup available. They both are also compatible with the intended environment and with other devices.

Spectrum Medical Ltd's Quantum Workstation (K163657) and Quantum Workstation 12.1" differ in that the Quantum Workstation 12.1" has a smaller touch screen display, operates in a landscape orientation, and currently does not allow for pump control on the Spectrum Medical Ltd Quantum Pump Console (K173834)

Table A: Comparison Table, Quantum Workstation vs. Quantum Workstation 12.1"

Device	Predicate Device	Proposed Device
Name	Quantum Workstation	Quantum Workstation 12.1"
510(k) Number	K163657	To be assigned
Manufacturer	Spectrum Medical Ltd Gloucester, England	Same
Intended Use	Extracorporeal monitoring of blood oxygen saturation, haematocrit and haemoglobin levels	Same
Clinical Application	Online monitoring of extracorporeal arterial and venous blood lines, and hematocrit and hemoglobin levels using sensor probes attached to the external surface of blood tubing	Same
Clinical Setting / Sites of Use	Hospital	Same
Target user	Perfusionist	Same
Target patient population	Patients (all ages, both genders) undergoing extracorporeal circulation	Same
Principal of Operation / Mechanism of Action Blood oxygen saturation (SO_2 %)	Comparison of the different patterns of absorbance of visible light reflected from oxy and deoxy forms of hemoglobin Single synchronization with reference blood gas analyzer; independent of blood flow, blood temperature, and hemodilution	Same
Principal of Operation / Mechanism of Action Haemoglobin (Hb) / Haematocrit (Hct)	Measures hemoglobin concentration by transmitting infrared light through the blood tube and quantifying the level of signal attention with a photodiode Calculates hematocrit from hemoglobin measurement	Same

Device	Predicate Device	Proposed Device
Performance	SO_2 Range = 20-100% Range Temperature = 15-37°C Mean Offset = 0.48 Standard Deviation = ±1.90 Hb / Hct Range: 5-15 g/dL / 15-45% (for 9/16" OD tube size) 5-16.6 g/dL / 15-50% (for all other sensors: 5/16", 3/8", 7/16" OD tube size) Range Temperature = 15-37°C Mean Offset = 0.03 Standard Deviation = ±0.60	Same
Human Factors	Touch screen display showing individual and trend readings with alarm settings Flash memory storage for recording case history No recalibration required due to negligible drift Also allows for display of 3rd-party data without alarms	Same general human factors features, however does not currently allow 3rd party data to display
Touchscreen	15" portrait	12.1" landscape
Design	General design features (weight)	Same general design features Small differences in weight
Compatibility with Intended Environments	Used in surgical environments and conforms to 60601 electrical safety and EMC requirements	Same
Battery Backup	Two-hour minimum life via two Lithium-Ion batteries	Same
Wireless Connectivity	Wi-Fi	Same
Wired Connectivity	3 USB / 8 Spectrum Accessory Ports (SAPs) (Allows connectivity to 3rd-party devices for data display / graphing; alarms are not associated with these data)	3 USB / 8 Spectrum Accessory Ports (SAPs) (Currently does not allows connectivity to 3rd-party devices for data display / graphing; alarms are not associated with these data)
Disposable / Reusable	Not applicable (No patient-contacting parts)	Same

Device	Predicate Device	Proposed Device
FDA-Recognized Standards Met	Electrical Safety: AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012 including relevant clauses of IEC 60601-2-49:2011 Electromagnetic Compatibility: IEC 60601-1-2:2014 Other: IEC 60601-1-6:2010 + A1:2013 IEC 60601-1-8:2006 + A1:2012 IEC 62133:2012 AAMI ANSI IEC 62304:2006 IEC 62366:2007+A1:2014 ISO 14971:2007	Electrical Safety: AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012 including relevant clauses of IEC 60601-2-49:2011 Electromagnetic Compatibility: IEC 60601-1-2:2014 Other: IEC 60601-1-6:2010 + A1:2013 IEC 60601-1-8:2006 + A1:2012 IEC 62133:2012 AAMI ANSI IEC 62304:2006 IEC 62366:2007+A1:2014 ISO 14971:2007

VII. PERFORMANCE DATA – NON-CLINICAL TESTING

No animal testing was submitted to support the substantial equivalence of the Quantum Workstation 12.1” to the Quantum Workstation (K16357).

The following bench performance testing was performed to support the substantial equivalence of the Quantum Workstation 12.1” to the Quantum Workstation (K163657):

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing, including defibrillator protection and electrosurgery interference requirements, were conducted on the Quantum Workstation 12.1” and its accessories. The system complies with the following safety and emissions standards:

- AAMI ANSI ES60601-1:2005/(R)2012 + A1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2010 + A1:2013
- IEC 60601-1-8:2006 + A1:2012
- IEC 60601-2-49:2011

Mechanical testing

In addition to the mechanical tests included in the 60601 tests, the following mechanical tests were performed on the Quantum Workstation 12.1”:

- screen impact test for the touch screen,
- effects of cleaning products on the enclosure material and labels / markings, and
- product function after exposure to non-operational (storage and transport) environmental requirement extremes of temperature and humidity.

Software verification and validation testing

The software for the Quantum Workstation 12.1” and its predicate, Quantum Workstation 12.1”, were determined to be Class B software (non-serious injury is possible) per IEC 62304:2006 because, if the Quantum Workstation (K163657) or Quantum Workstation 12.1” display faulty or incorrect data, clinicians will rely on other medical devices in the operating room to confirm the diagnostic values. Therefore, there are no risks of death or serious injury possible from the device’s software.

System-level and subcomponent-level software verification and validation testing were conducted for the Quantum Workstation.

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the Quantum Workstation 12.1” to the Quantum Workstation (K163657).

IX. CONCLUSIONS

There are minor differences between the Quantum Workstation 12.1” and the predicate device (Quantum Workstation (K163657)) in technological characteristics with regards to, touch screen display size, operational orientation, HLM pump control. However, these differences do not raise new questions of safety or effectiveness. Thus, the device characteristics compared in **Table A** and the results of the bench performance tests confirm that the Quantum Workstation 12.1” is substantially equivalent to the Quantum Workstation (K163657).