DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 18, 2017

Spectrum Medical, Ltd.
Mark Drain
Chief Financial Officer
Harrier 4, Meteor Business Park
Cheltenham Road East
Gloucester, GL2 9QL
England

Re: K163657
Trade/Device Name: Quantum Workstation
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor
Regulatory Class: Class II
Product Code: DRY
Dated: December 16, 2016
Received: December 23, 2016

Dear Mr. Drain:

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. 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.

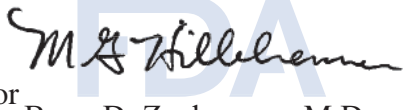
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163657

Device Name
Quantum Workstation

Indications for Use *(Describe)*

The intended use of the Quantum Workstation 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 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 (%)

The Workstation 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

510(k) Number: K163657

I. SUBMITTER

Spectrum Medical Ltd
Harrier 4, Meteor Business Park,
Cheltenham Road East,
Gloucester. GL2 9QL
England

Phone: +44 (0) 1242 650 120
Fax: +44 (0) 8452 808 127

Contact Person: Mr. Mark Drain, Chief Financial Officer

Date Summary Prepared: January 17, 2017

II. DEVICE

Proprietary Name:	Quantum Workstation
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 M2 Monitor (K071725)

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 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 consists of a pole-mounted 14 ¾" portrait high definition touch screen. The touch screen displays individual and trend readings with alarm settings. Third party data may also be displayed (without alarms). The Quantum Workstation has a Wi-Fi adapter and provides memory storage via an SD (Secure Digital) card. The Quantum Workstation 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 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 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 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 is configured to measure and display the following measurements:

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

The Workstation 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

As shown in **Table A**, Spectrum Medical Ltd's M2 Monitor and Quantum Workstation 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 M2 Monitor and Quantum Workstation differ in that the Quantum Workstation has a larger touch screen display, has additional USB and LAN ports, allows for display of 3rd-party data without alarms, and provides additional graphs with a pinch action feature for graph resizing. The M2 Monitor uses three nickel hydride batteries to provide an ~1-hour battery life whereas the Quantum Workstation uses two lithium-ion batteries to provide a 2-hour minimum battery life.

Table A: Comparison Table, M2 Monitor vs. Quantum Workstation

Device	Predicate Device	Proposed Device
Name	M2 Monitor	Quantum Workstation
510(k) Number	K071725	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 Device uses equivalent Hb / SO_2 sensor to M2 Monitor (has improved electrical isolation and different colored cable boot)
Principal of Operation / Mechanism of Action Hemoglobin (Hb) / Hematocrit (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 uses equivalent Hb / SO_2 sensor to M2 Monitor (has improved electrical isolation and different colored cable boot)

Device	Predicate Device	Proposed Device
Performance	$\underline{SO_2}$ 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	Same general human factors features Also allows for display of 3rd-party data without alarms
Touchscreen	10.4" landscape	15" portrait
Design	Compact, lightweight, pole mounted on clamp	Same general design features Small differences in weight and pole clamp design
Compatibility with Intended Environments	Used in surgical environments and conforms to 60601 electrical safety and EMC requirements Compliant with 2nd edition IEC 60601 (and 3rd edition in a later update)	Same general electrical compatibility features Compliant with 3rd edition IEC 60601
Battery Backup	One-hour life via three Nickel Hydride batteries	Two-hour minimum life via two Lithium-Ion batteries
Wireless Connectivity	Wi-Fi and Bluetooth	Wi-Fi
Wired Connectivity	2 USB / 3 Accessory Ports	3 USB / 8 Spectrum Accessory Ports (SAPs) (Allows connectivity to 3rd-party devices for data display / graphing; alarms are not associated with these data) SAPs are for future use
Disposable / Reusable	Not applicable (No patient-contacting parts)	Same

Device	Predicate Device	Proposed Device
FDA-Recognized Standards Met	Electrical Safety: *With 510(k) submission:* IEC 60601-1 2nd Edition 1988 with A1:1991 and A2:1995 including relevant clauses of IEC 60601-2-49:2001 clauses 5, 6, 14, 17, 19, 20, 44, 49 & 56 *Updated in 2013:* IEC 60601-1 3rd Edition; UL 60601-1/CAN/CSA C22.2 No. 601.1	Electrical Safety: AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012 including relevant clauses of IEC 60601-2-49:2011
	Electromagnetic Compatibility: *With 510(k) submission:* IEC 60601-1-2:2001 Clause 36 only (EMC) *Updated in 2013:* IEC 60601-1-2:2007	Electromagnetic Compatibility: IEC 60601-1-2:2014
	Other: IEC 60601-1-8:2006 IEC 62133:2002 AAMI ANSI IEC 62304:2006 ISO 14971:2000 + A1:2003 *Updated in 2013:* ISO 14971:2007	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 to the M2 Monitor.

The following bench performance testing was performed to support the substantial equivalence of the Quantum Workstation to the M2 Monitor:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing, including defibrillator protection and electrosurgery interference requirements, were conducted on the Quantum Workstation 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:

- 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 and its predicate, M2 Monitor, were determined to be Class B software (non-serious injury is possible) per IEC 62304:2006 because, if the M2 Monitor or Quantum Workstation 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.

A usability validation test was also performed for the Quantum Workstation user interface.

SO_2 and Hb performance testing

In vitro testing was performed to confirm, as shown in **Table A**, that the SO_2 and Hb (with calculated Hct) functional performance for the Quantum Workstation was unchanged from the M2 Monitor.

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the Quantum Workstation to the M2 Monitor.

IX. CONCLUSIONS

There are minor differences between the Quantum Workstation and the predicate device (M2 Monitor) in technological characteristics with regards to battery type and life, touch screen display size, number of USB and LAN ports, pinch action for graph resizing, and display of 3rd-party data without alarms. 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 is substantially equivalent to the M2 Monitor.