July 8, 2025

Spectrum Medical Ltd.
Asia Lukuc
Regulatory Affairs Manager
Harrier 4, Meteor Business Park, 128 Cheltenham Road East
Gloucester, GL2 9QL
United Kingdom

Re: K240908
Trade/Device Name: Quantum Micro-Cardioplegia Delivery System; Quantum Micro-Cardioplegia Delivery Module (QMCDM)
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary bypass heat exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: April 2, 2025
Received: April 10, 2025

Dear Asia Lukuc:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Rachel E. Neubrander -S

for Nicole Gillette
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240908

Device Name

Quantum Micro-Cardioplegia Delivery System;
Quantum Micro-Cardioplegia Delivery Module (QMCDM)

Indications for Use *(Describe)*

The Quantum Micro-Cardioplegia Delivery System is intended for delivery of micro-cardioplegia to the heart during open heart surgery lasting up to six hours in duration. It is intended 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.

K240908

510(k) Summary

Prepared on: 2024-04-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Spectrum Medical Ltd.
Applicant Address	Harrier 4, Meteor Business Park, 128 Cheltenham Road East Gloucester GL2 9QL United Kingdom
Applicant Contact Telephone	+44 1242 386603
Applicant Contact	Ms. Asia Lukuc
Applicant Contact Email	asia.lukuc@spectrummedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Quantum Micro-Cardioplegia Delivery System; Quantum Micro-Cardioplegia Delivery Module (QMCDM)
Common Name	Cardiopulmonary bypass heat exchanger
Classification Name	Heat-Exchanger, Cardiopulmonary Bypass
Regulation Number	870.4240
Product Code(s)	DTR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201984	MPS3 ND Myocardial Protection System	DTR
K172831	Perfusor Space Syringe Infusion Pump System	FRN

Device Description Summary

21 CFR 807.92(a)(4)

The Quantum Micro-Cardioplegia Delivery System is intended to assist in arresting a beating heart during cardiac surgery through controlled delivery of cardioplegia. The system consists of the Quantum Workstation, Quantum Micro-Cardioplegia Delivery Module, Quantum Roller Pump 4", Quantum Diagnostic/Venilation Module, and Quantum Pureflow Cardioplegia Heat Exchanger. The Quantum Micro-Cardioplegia Delivery Module was developed to supplement the existing Quantum technology and to allow users a more integrated way of managing microplegia delivery during cardiopulmonary bypass.

The Quantum Micro-Cardioplegia Delivery System is intended specifically for procedures where microplegia (i.e., whole blood cardioplegia) strategy is used. The Quantum Micro-Cardioplegia Delivery Module adds cardioplegia drugs (i.e., arrest agent and additive) to the main carrier solution (blood) which is circulated by a Quantum Roller Pump. The two devices, working in unison and controlled by the Quantum Workstation, deliver cardioplegia to the patient's heart.

The premise of the Quantum Micro-Cardioplegia Delivery System is to interlock forward cardioplegia flow with medication delivery rates, ensuring delivery of arrest agent at a given ratio to the blood. The system includes a separate, dedicated heat exchanger, which is intended to be fitted in the cardioplegia blood line to allow for temperature regulation of the cardioplegia solution. The heat exchanger can be connected to any available heater cooler device which will manage the temperature regulation.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Quantum Micro-Cardioplegia Delivery System is intended for delivery of micro-cardioplegia to the heart during open heart surgery

lasting up to six hours in duration. It is intended to be used by an experienced and trained clinician. It is not intended to be used by a patient or other untrained personnel.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The primary predicate and proposed devices have substantially equivalent indications for use. Both devices are intended to deliver microplegia (a type of cardioplegia also referred to as minicardioplegia or whole blood cardioplegia) to the heart during open-heart surgery. The difference between the indications for use of the predicate and the subject device is that the MPS 3 ND (predicate) also includes delivery of cardioplegia when strategies other than microplegia are used (i.e., ratio cardioplegia or all crystalloid cardioplegia). Both the primary predicate and proposed devices are used in a hospital operating room by a perfusionist on patients of all ages and genders.

The reference device has much broader indications for use (delivery of fluid and blood) than the proposed device.

Technological Comparison

21 CFR 807.92(a)(6)

Both the primary predicate and proposed devices have independent control of the arrest agent and additive. In both devices, the delivery of arrest agent and additive is interlocked with the blood flow in the cardioplegia line. The infusion mechanism (operating principle), however, is different between the primary predicate and the proposed device. The Quest MPS3 ND uses a single piston pump driven by a stepper motor for arrest agent/additive delivery and a double piston pump for blood delivery. The Quantum Micro-Cardioplegia Delivery Module uses a syringe plunger driven by a stepper motor with a lead screw for arrest agent/additive delivery, and a roller pump for blood (mixed with cardioplegia drugs) delivery. The linear pump used in the Quantum Micro-Cardioplegia Module is equivalent to the reference device (Perfusor Syringe Infusion Pump by B. Braun Medical).

Additionally, while the primary predicate (MPS3 ND) delivers cardioplegic agents from a pouch type container, the reference device (Perfusor), like the Quantum Micro-Cardioplegia Delivery Module, uses a syringe to hold the medication/agent.

Both the primary predicate and proposed device monitor the following parameters: drug concentrations (set parameters), flow rates, pressures, and temperature. Both the MPS 3 ND predicate device and the Quantum Micro-Cardioplegia Delivery System rely on external heater-cooler units to regulate the temperature of the solution that is being delivered to the patient. Both devices use external heat exchangers.

The units of delivery of arrest agent and additive are the same between the primary predicate and proposed device. The concentration range of arrest agent in the primary predicate is 0-40 mEq/L whereas in the proposed device it is 0-25 mEq/L.

Both the primary predicate and proposed devices use an integrated touchscreen to control the device functions, whereas the proposed Quantum Micro-Cardioplegia Delivery System can also display information on the much larger screen on the Quantum Workstation to make it easier to see while controlling other parameters of the cardiopulmonary bypass. Information such as temperature, flow, pressure, drug concentration, and delivery route are displayed to the user. Both devices can deliver the same concentration range of arrest agent and additive with the same infusion accuracy.

The primary predicate and proposed device use a variety of accessories. The primary predicate includes disposable cardioplegia delivery sets and extension lines and uses a disposable water circuit with dripless connectors. Similarly, the syringes and extension lines compatible for use with the Quantum Micro-Cardioplegia Delivery System are disposable.

Results from the testing conducted on the subject device demonstrate that the differences in technological characteristics between the subject device and the predicate device do not raise different questions of safety and effectiveness. Thus the Quantum Micro-Cardioplegia Delivery System is substantially equivalent to the predicate device (MPS 3 ND).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

A suite of nonclinical tests was performed for the Quantum Micro-Cardioplegia System to support a determination of substantial equivalence to the predicate device.

The bench and nonclinical tests included:
- Electronic/PCBA Tests
- IEC 60601-1 Electrical Safety Tests
- IEC 60601-1-2 Electromagnetic Compatibility Tests
- Functional/Performance Tests
- Software Verification Tests
- Human Factors/Usability Test
- Environmental/Storage, Transportation, and Cleaning Tests