June 19, 2020

Quest Medical, Inc.
Tosan Onosode
Regulatory Affairs Supervisor
One Allentown Parkway
Allen, Texas 75002

Re: K200438
Trade/Device Name: MPS 3 Myocardial Protection System
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II
Product Code: DTR, DWC
Dated: May 19, 2020
Received: May 20, 2020

Dear Tosan Onosode:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200438

Device Name
MPS 3 Myocardial Protection System

Indications for Use *(Describe)*

The Quest Medical MPS 3 Myocardial Protection System, consisting of the MPS 3 Console, the MPS 3 Controller, and the MPS 3 Disposables (MPS 3 Delivery Set and optional Accessories) together is intended for use by perfusionists and physicians to deliver whole blood (from any arterial source) and/or cardioplegia solutions to the heart during open-heart surgery on either an arrested or beating heart for use up to six hours in duration.

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) Notification K200438

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002-4211
USA
Phone: 972-332-6338
Fax: 972-390-2881

Contact Person:
Tosan Onosode
Regulatory Affairs Supervisor
Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002-4211
USA
Phone: 972-332-6338
Fax: 972-390-2881
Email: tonosode@questmedical.com

Date Prepared: February 21, 2020

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

MPS 3 Myocardial Protection System (MPS 3)

Generic/Common Name:

Cardiopulmonary Bypass Heat Exchanger

Classification:

Class II per 21CFR§870.4240

Product Code:

DTR, DWC

PREDICATE DEVICE(S) [807.92(a)(3)]

Quest Medical, Inc., MPS®2 Myocardial Protection System (K173716).

DEVICE DESCRIPTION [807.92(a)(4)]

The MPS 3 Myocardial Protection System (MPS 3) is a software controlled system designed to aid the perfusionist in cardioplegia delivery to a patient during Cardiopulmonary Bypass Surgery. The MPS 3 System combines blood from the heart-lung machine and crystalloid from the IV-bag in a specified ratio and then adds in the drug (arrest or additive agent) for delivery to the patient. The MPS 3 System consists of a reusable MPS 3 Console, a reusable MPS 3 Controller, and single use MPS 3 Disposables.

The MPS 3 Console incorporates two Blood/Crystalloid pumps (B/C pumps), a temperature- controllable water circulation system, pressure and temperature monitors, a sensor interface, an arrest agent pump, an additive pump and ultra-sonic air detection sensors. The MPS 3 Console monitors and controls the blood:crystalloid ratio, drug concentration, flow rate, pressure, temperature, and delivery route of the cardioplegia solution delivered to the patient.

The MPS 3 Controller is a touchscreen user interface utilized by the operator to select all parameters, initiate/stop cardioplegia delivery, monitor delivery parameters and view/save relevant case information and data.

The MPS 3 Disposables includes single use delivery sets (also known as the "MPS 3 Delivery Sets"), delivery set accessories and blood bypass tubing. The MPS 3 Delivery Sets and accessories consist of a flexible cassette, a heat exchanger, drug cartridges and relevant tubing and connectors used to complete the cardioplegia circuit for use with the MPS 3 Console. The blood bypass tubing is used as a backup in the event the MPS 3 Console becomes unusable.

INDICATIONS FOR USE [807.92(a)(5)]

The Quest Medical MPS 3 Myocardial Protection System, consisting of the MPS 3 Console, the MPS 3 Controller, and the MPS 3 Disposables (MPS 3 Delivery Set and optional Accessories) together is intended for use by perfusionists and physicians to deliver whole blood (from any arterial source) and/or cardioplegia solutions to the heart during open-heart surgery on either an arrested or beating heart for use up to six hours in duration.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE [807.92(a)(6)]

In demonstrating substantial equivalence of the MPS 3 Myocardial Protection System to the predicate MPS 2 Myocardial Protection System, Quest Medical considered the following aspects:

- Intended Use/Indications for Use
- Anatomical Site
- Patient Population
- Principles of Operation
- Design Features/Technological Characteristics
- Performance Specifications
- Materials
- Labeling

The MPS 3 has the same Indications for Use, principles of operation, duration of use, and is used in the same anatomical site in the same patient population as the predicate device. The MPS 3 has similar design features, technological characteristics, performance specifications, patient contacting materials and labeling as the predicate device. The differences in the technological characteristics between the MPS 3 and the predicate do not raise different questions of safety or effectiveness. Thus, the MPS 3 Myocardial Protection System (MPS 3) is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(b)]

All necessary bench, nonclinical, and human factors testing was conducted on the MPS 3 Myocardial Protection System (MPS 3) to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]

The bench and nonclinical tests included:

- Sterilization, Shelf-Life, and Packaging Testing
- Cleaning and Disinfection Validation
  - Cleaning and intermediate level disinfection validation testing was conducted to demonstrate the adequacy of the external surface cleaning and disinfection instructions contained in the MPS 3 Operations Manual.
  - Intermediate level disinfection validation testing was conducted on the water circulation system to demonstrate the effectiveness of the disinfection instructions contained in the MPS 3 Operations Manual.
  - Long term (6 months) disinfection validation study was conducted to evaluate the effectiveness of the disinfection procedures in preventing or mitigating biofilm formation in the water circulation system.
- Biocompatibility Testing (Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Pyrogenicity, Hemocompatibility, Genotoxicity)
- Software Verification Tests

- IEC 60601-1 Electrical Safety Tests
- IEC 60601-1-2 Electromagnetic Compatibility Tests
- System Performance Tests
- IEC 62133 Battery Compliance Tests
- Alarm Verification Tests
- Altitude Test
- Reliability Tests
- Mechanical Hemolysis Test
- Human Factors/Usability Test
- Shipping/Transit Tests
- Disposables Performance Test
    - Leak Test
    - Tubing Bonding Strength
    - Tubing Break Force
    - Tubing Bend Radius
    - Priming Volume
    - Simulated Use
    - Burst Pressure
    - Activation Force
    - Retraction Force
    - Blood Side Leak
    - Water Side Leak
    - Port blockage
    - High Pressure Leak
    - Efficiency Test
    - Pressure Drop
    - Corrosion Test
    - Clamp Test
- Animal Testing

Clinical Testing Summary [807.92(b)(2)]

Not applicable. Clinical testing was not performed to support this 510(k) submission.

The collective results of the performance testing demonstrate that the MPS 3 Myocardial Protection System (MPS 3) meets the established specifications necessary for consistent performance during its intended use. In addition, the collective performance testing demonstrate that the Quest MPS 3 Myocardial Protection System (MPS 3) does not raise different questions of safety or effectiveness for Cardiopulmonary Bypass Surgery when compared to the predicate device.

CONCLUSIONS [807.92(b)(3)]

The results from the performance testing support the conclusion that the MPS 3 Myocardial Protection System (MPS 3) device is substantially equivalent to the legally marketed predicate device.

SUMMARY

The MPS 3 Myocardial Protection System (MPS 3) is substantially equivalent to the predicate device.