October 1, 2018

Quest Medical, Inc.
% Ronald Warren
Sr. Director, Regulatory Affairs
Experien Group
224 Airport Parkway
San Jose, California 95110

Re: K173716
Trade/Device Name: MPS2 Myocardial Protection System Console
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II
Product Code: DTR, DWC
Dated: August 22, 2018
Received: August 23, 2018

Dear Ronald Warren:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173716

Device Name
MPS2 Myocardial Protection System

Indications for Use *(Describe)*

The Quest Medical MPS®2 Myocardial Protection System, consisting of the MPS2 console and the MPS Delivery Set 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

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"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 - K173716

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
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Date Prepared: September 25, 2018

DEVICE INFORMATION [807.92(a)(2)]

Classification:
Class II per 21CFR§870.4240

Product Code:
DTR

Trade Name:
MPS2 Myocardial Protection System Console

Generic/Common Name:
Myocardial Perfusion System

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

MPS2 Myocardial Protection System Console (K041979)

DEVICE DESCRIPTION [807.92(a)(4)]

The MPS 2 console is a single device for myocardial perfusion that incorporates several different functions: heat exchanger, temperature control, pressure control, flow rate control, automatic priming and air detection / removal, and 3 flow modes - normal, cyclic, low volume.

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

The MPS System, MPS console and the MPS delivery set used together, is 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.

The proposed MPS2 will have the same indication for use as the predicate MPS2 system as cleared under K041979.

SUBSTANTIAL EQUIVALENCE

This labeling modification for the MPS2 is being submitted in order to provide end-user instructions related to the disinfection of the MPS2 water circulation system. Due to emerging concerns with sources of patient infection during cardiothoracic surgery and increased efforts to reduce biofilm formation in devices that may contribute to microbial contamination in the clinical setting, many perfusionists and other end-users are now requesting validated disinfection protocols. To address this clinical need, Quest Medical has validated a disinfection procedure, the details of which are to be added to the product labeling. This proposed change to product labeling summarized in this Traditional 510(k) premarket notification does not affect the intended use or the indication for use, and does not alter the fundamental scientific technology of the device. The modified MPS2 shares the same indication for use and the same technological characteristics as the predicate device. Therefore, based on the similarities between the two devices, the modified MPS2 is substantially equivalent to the predicate MPS2 device previously cleared under K041979.

PERFORMANCE DATA [807.92(b)]

All necessary bench testing was conducted on the proposed MPS2 to support a determination of substantial equivalence to the predicate device. The disinfection method added to the product labeling was validated based on relevant guidance from AAMI TIR12, AAMI TIR30, FDA Guidance on Reprocessing Medical Devices, and the FDA Advisory Panel meeting on Circulatory System Devices, which occurred on June 2-3, 2016. The disinfection method meets requirements for an intermediate level of disinfection on *Pseudomonas aeruginosa* and *Mycobacterium chimaera*. The disinfection validation demonstrated a 6-Log reduction against the *P. aeruginosa* and a 3-Log reduction against *M. chimaera*. The prescribed disinfectant and microbial growth inhibitor were shown to be compatible with the materials of the water circulation system. In addition, this 510(k) notification was supported with results from surface cleaning and disinfection testing and heat exchanger performance testing.

SUMMARY

The proposed MPS2 device is substantially equivalent to the predicate device.