May 6, 2022

Spectrum Medical Ltd.
Colleen Powell
Director, Regulatory Affairs
Harrier 4, Meteor Business Park, Cheltenham Road East
Gloucester, Gloucestershire GL29QL
United Kingdom

Re: K212657
Trade/Device Name: Quantum Heater-Cooler
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: April 5, 2022
Received: April 6, 2022

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/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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
Quantum Heater-Cooler

Indications for Use *(Describe)*
The Spectrum Medical Quantum Heater-Cooler is intended to provide temperature-controlled fluid to compatible Quantum PureFlow heat exchanger devices (cardiopulmonary bypass heat exchangers and cardioplegia heat exchangers) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.
The Quantum Heater-Cooler is only intended to be used by trained Clinicians in a clinical environment.

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

## I. SUBMITTER

| | |
|---|---|
| Name: | Spectrum Medical Ltd |
| Address: | Harrier 4, Meteor Business Park<br>Cheltenham Road East<br>Gloucester GL2 9QL<br>United Kingdom |
| Contact Person: | Colleen Powell, Director of Regulatory Affairs |
| Phone: | +44 (0) 1242 650 120 |
| Fax: | +44 (0) 8452 808 127 |
| Date Summary Prepared: | 20 August 2021 |

## II. DEVICE

| | |
|---|---|
| Proprietary Name: | Quantum Heater-Cooler |
| Common Name: | Cardiopulmonary bypass system heating/cooling unit |
| Classification Name: | Controller, Temperature, Cardiopulmonary Bypass |
| Regulatory Class: | II |
| Product Code: | DWC |
| Panel: | Office of Health Technology 2 (OHT2 Cardiovascular Devices) / Division of Health Technology 2B (Circulatory Support, Structural and Vascular Devices) |

## III. PREDICATE DEVICE

The predicate device for this submission is the Sorin/LivaNova Stöckert Heater-Cooler System 3T (K052601).

## IV. DEVICE DESCRIPTION

The Quantum Heater-Cooler consists of the following components:

- Quantum Heater-Cooler Unit (including connection hoses and heat transfer fluid)
- Quantum Pure Flow Heat Exchangers (standard and cardioplegia, manufactured by Qura S.r.l.)
- External cold storage charger

The Quantum Heater-Cooler is intended for cooling and warming patients during cardiothoracic surgeries requiring cardiopulmonary bypass with extracorporeal circulation (procedures lasting six (6) hours or less). The system regulates the temperature of circulating blood and cardioplegia solution using a

proprietary glycol-based heat transfer fluid. Thermal energy carried by the heat transfer fluid is transferred from the heater-cooler unit to the patient perfusion circuit via Quantum PureFlow heat exchangers specifically developed for both the arterial and cardioplegia circuits. The heater-cooler, in conjunction with the heat exchangers, forms a closed circuit and no direct contact with the patient's blood or body fluids takes place at any time.

Heating of the heat transfer fluid is accomplished through electrical heaters. For fluid cooling, the Quantum Heater-Cooler utilizes a Phase Change Material as a cold energy storage. This Phase Change Material needs to be routinely recharged between surgeries using an external cold storage charger outside of the operating room environment.

## V. INTENDED USE / INDICATIONS FOR USE

The Spectrum Medical Quantum Heater-Cooler is intended to provide temperature-controlled fluid to compatible Quantum PureFlow heat exchanger devices (cardiopulmonary bypass heat exchangers and cardioplegia heat exchangers) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.

The Quantum Heater-Cooler is only intended to be used by trained Clinicians in a clinical environment.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THEPREDICATE DEVICE

Spectrum Medical Ltd.'s Quantum Heater-Cooler and Sorin/LivaNova's Stöckert Heater-Cooler System 3T have the same intended use, indications for use, clinical setting, target user, target patient population, and principle of operation. They have the same temperature ranges and equivalent temperature accuracy.

However, the Quantum Heater-Cooler utilizes a proprietary glycol-based heat transfer fluid whereas the Stöckert system uses filtered tap water with hydrogen peroxide. The Quantum Heater-Cooler's heat transfer fluid has demonstrated that it mitigates the risk of contamination of the device by suppressing the growth of nontuberculous mycobacteria and other bacteria. The Quantum Heater- Cooler does not use a fan compressor to chill the heat transfer fluid like the Stöckert system but uses a Phase Change Material that is charged by an external cold storage charger outside of the operating room environment. Microbiological assay testing was performed on the Quantum Heater-Cooler, to demonstrate that aerosolization of *M. chimaera* (if present) is minimal.

The Quantum Heater-Cooler does not work with a heating/cooling blanket whereas the Stöckert Heater-Cooler System 3T does.

These differences in technological characteristics do not raise new issues of safety or effectiveness.

## VII. PERFORMANCE DATA – NON-CLINICAL TESTING

No animal testing was submitted to support the substantial equivalence of the Quantum Heater-Cooler and Sorin/LivaNova's Stöckert Heater-Cooler System 3T. The following non-clinical testing was performed to support the substantial equivalence of the Quantum Heater-Cooler to the legally marketed predicate:

- Electrical safety
- Electromagnetic compatibility (EMC)
- Electrosurgery interference
- Hardware testing
- Aerosolization testing
- Software verification and validation
- Evaluation of heat transfer fluid for microbial suppression
- Shelf life testing of heat transfer fluid
- Usability evaluation

## VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the Quantum Heater-Cooler to the Sorin/LivaNova Stöckert Heater-Cooler System 3T.

## IX. CONCLUSIONS

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Quantum Heater-Cooler has been shown to be substantially equivalent to a legally marketed predicate device.