April 19, 2023

Medtronic Inc.
Anna Wetherille
Sr. Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K223168
Trade/Device Name: Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: QWF
Dated: March 15, 2023
Received: March 16, 2023

Dear Anna Wetherille:

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,

Kathleen M. Grunder -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223168

Device Name
Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface

Indications for Use *(Describe)*
The Medtronic tubing and accessories sets for extracorporeal membrane oxygenation (ECMO) with Balance biosurface are indicated for use in ECMO and extracorporeal life support (ECLS) procedures for adult patients with acute respiratory failure or acute cardiopulmonary failure when other available treatment options have failed, and when continued clinical deterioration is expected or the risk of death is imminent.

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.

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510(k) Summary of Safety and Effectiveness

Date Prepared: **April 18, 2023**

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
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Establish Registration Number: 2184009

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Trade Name: Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) Balance™ Biosurface

Common Name: Extracorporeal Life Support Circuit and Accessories

Classification Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure

Classification: Class II (with special controls)

Regulation Number: 21 CFR 870.4100

Product Code: QWF

Name of Predicate Device: FDA Final Order 81 FR 7451, February 12, 2016

Name of Reference Device: Tubing Pack (K171979)

Device Description:

The Medtronic Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface ("eSets") contain components used to prepare an extracorporeal circuit for extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS) procedures.

The Base eSet Model BB22LSB contains a preassembled drainage and return loop, tubing assemblies, and other components used to prepare a basic extracorporeal circuit.

The Accessory eSet Model BB22LSA contains nonstandard components to supplement the basic extracorporeal circuit, as needed per case and hospital protocols.

This product is nonpyrogenic, is intended for single use, and has been sterilized using ethylene oxide. Maximum transit temperature: 50°C (122°F). Standard storage conditions are sufficient to safeguard the device. Store the device in the original packaging at room temperature in a dry place.

Bench studies were performed after device preconditioning including exposure (up to 21 days) to simulated in vivo use conditions to demonstrate safety and reliability.

Indication for Use:

The Medtronic tubing and accessories sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance biosurface are indicated for use in ECMO and extracorporeal life support (ECLS) procedures for adult patients with acute respiratory failure or acute cardiopulmonary failure, when other available treatment options have failed, and when continued clinical deterioration is expected or the risk of death is imminent.

Comparison to Predicate (Special Controls):

Substantial equivalence evaluation includes a comparison to requirements in the FDA Final Order 81 FR 7451, February 12, 2016, as well as a comparison to the Reference Device. Per FDA Final Order (81 FR 7451) membrane lung devices for long-term pulmonary support, a preamendment class III device, as extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure, were redesignated and reclassified to class II (special controls) in patients with acute respiratory failure or acute cardiopulmonary failure where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

The Medtronic Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface device meets all special controls identified in 21 CFR 870.4100, as follows:

- Technological Characteristics: The geometry and design parameters of the subject device are consistent with the device's intended use in extracorporeal support procedures, and the device is compatible with the other devices and accessories in the extracorporeal circuit.
- Biocompatibility: The subject device is demonstrated to be biocompatible in accordance with ISO 10993-1:2018 and with FDA guidance document Use of

International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (4 September 2020).

- Sterility and Shelf-life: Sterilization adoption evaluation and shelf-life testing demonstrate that the subject device maintains its sterility, integrity, durability, and reliability over the stated shelf life of the device.
- Non-clinical Performance: Substantial equivalence of the performance characteristics is demonstrated on bench, mechanical integrity, durability, and reliability testing.
- Labeling: The Instructions for Use include a detailed summary of the non-clinical evaluations pertinent to use of the device in an extracorporeal circuit and adequate instructions with respect to anticoagulation, circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure.

Comparison to Reference Device:

A comparison of the Medtronic Tubing and Accessories Sets for ECMO with Balance™ Biosurface to the reference device indicates the following similarities:

- Similar intended use, the only exception is the extended duration of extracorporeal support.
- Same technological characteristics
- Same operating principle
- Same design features
- Similar materials, the only exception is the new TOTM plasticizer used for the prolonged use components
- Same shelf life, the subject device has a 2-year shelf life

Summary of Performance Data

In vivo pre-clinical and clinical studies involving patients or animals were not necessary to demonstrate the safety and performance of the subject device. Pre-clinical bench testing was used to verify the performance characteristics of this device.

The following preclinical bench studies were conducted:

- 21-day Simulated use durability testing
- Tensile strength after life conditioning (long term use)
- Pressure test after life conditioning (long term use)
- Functional testing
- Kink testing
- Blood trauma testing
- Coating coverage

Conclusion:

The data included in this submission are sufficient to demonstrate that the Medtronic Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface meets the special controls in FDA's Final Order (81 FR 7451, Redesignation as Extracorporeal Circuit and Accessories For Long- term Respiratory/cardiopulmonary Failure (ECMO), February 12, 2016), to connect perfusion devices and circulate blood as part of an extracorporeal circuit for use in Extracorporeal Membrane Oxygenation (ECMO) and Extracorporeal Life Support (ECLS) procedures.