January 14, 2022

Medtronic Inc.
Juli Rubin
Principal Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K201057
Trade/Device Name: Bio-Medicus Life Support Catheter and Introducer
Regulation Number: 21 CFR 21 CFR 870.4100
Regulation Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulatory Class: Class II
Product Code: QHW
Dated: January 4, 2022
Received: January 5, 2022

Dear Juli Rubin:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201057

Device Name
Bio-Medicus Life Support™ Catheter and Introducer

Indications for Use *(Describe)*

The Bio-Medicus Life Support catheters and introducers are single-lumen drainage or reinfusion peripheral-access catheters to be used in ECMO or ECLS with an extracorporeal circuit intended for use in adult and pediatric 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.

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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5.0 510(k) Summary of Safety and Effectiveness

Date Prepared:	**April 20, 2020**
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 **Establish Registration Number:** 2184009
Contact Person:	Juli Rubin, MBA, RAC **S**r. Principal Regulatory Affairs Specialist Phone: (763) 526-2357 Fax: (763) 367-8361 E-mail:juli.c.rubin@medtronic.com Kristyn Benson (Alternate) Sr. Regulatory Affairs Director Phone: (763) 526-2523 Email: kristyn.m.benson@medtronic.com
Trade Name:	Bio-Medicus Life Support™ Catheter and Introducer
Common Name:	Extracorporeal Life Support Single Lumen Catheter
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:	QHW
Name of Predicate Device:	FDA Final Order 81 FR 7451, February 12, 2016
Name of Reference Devices:	Bio-Medicus Adult Cannulae and Introducer (K142673) Bio-Medicus Pediatric Arterial and Femoral Cannula (K143083) Bio-Medicus Adult Cannulae and Introducer (K180453)

Device Description:

The Bio-Medicus Life Support™ catheter is a single-lumen catheter used to drain or reinfuse blood. The introducer facilitates proper insertion and placement of the appropriately sized catheter over a guidewire within the vessel. These devices are intended to perfuse vessels or organs in conjunction with extracorporeal support, including Extracorporeal Membrane Oxygenation (ECMO) and Extracorporeal Life Support (ECLS). Catheter models with tip lengths of 18 cm (7.09 in), 50 cm (19.7 in), or 55 cm (21.7 in), with and without additional side holes may be used as either drainage or reinfusion catheters.

These devices are sterile, nonpyrogenic, disposable, intended for single use only. Bench studies were performed after device preconditioning including exposure (21 days) to simulated in vivo use conditions to demonstrate safety and reliability. Do not store the product above 25°C (77°F).

Indication for Use:

The Bio-Medicus Life Support catheters and introducers are single-lumen drainage or reinfusion peripheral-access catheters to be used in ECMO or ECLS with an extracorporeal circuit intended for use in adult and pediatric patients with acute respiratory or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

Contraindications:

Alone, the catheter and introducer are not medical treatment devices. The introducer is to be used only with the appropriately sized Bio-Medicus Life Support catheter. These devices are intended for use only as indicated in these instructions for use. Do not insert the catheter in a vessel that has arterial dissection or severe peripheral atherosclerosis.

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 Devices. 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 Bio-Medicus Life Support™ Catheter and Introducer 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 as a prolonged use device in accordance with ISO 10993-1:2009 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" (16 June 2016).

- 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.
- *In vivo* Evaluation: *In vivo* evaluation demonstrates the subject device's performance over a 7-day duration of use.
- Labeling: The Instructions for Use include a detailed summary of the non-clinical and *in vivo* 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 Devices:

A comparison of the Medtronic Bio-Medicus Life Support Catheters and Introducers to the reference devices 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; the only exception is a slight increase in outer diameter (OD) of small sized devices to ensure durability throughout the duration of intended use. The inner diameter (ID) is identical to the reference device.
- Similar materials; the only exception is the catheter body blood-contacting material which has changed from polyurethane to a siloxane-urethane co-polymer, which provides a biostable surface for a longer-term use.
- Similar shelf life; the subject device has a 3-year shelf life, which is one year shorter than the reference device (4-year shelf life).

Summary of Performance Data

Per FDA Final Order (81 FR 7451), February 12, 2016, *in vivo* clinical studies involving patients are not necessary to demonstrate the safety and performance of the subject devices. Pre-clinical bench testing was used to verify the performance characteristics of this device. In vivo animal testing was also completed to establish substantial equivalence with the predicate regulation.

The following performance tests were conducted:

- 21-day Simulated use durability testing
  - Tensile strength after life conditioning (long term use)

  - Pressure test after life conditioning (long term use)
- Blood trauma testing
- Kink testing
- Birds Mouth testing
- ID occlusion due to suture ring
- Suture Collar Slide Force
- Introducer removal and insertion forces
- 7-day GLP *in vivo* study

Conclusion:

The data included in this submission are sufficient to demonstrate that the Medtronic Bio-Medicus Life Support Catheter and Introducer is substantially equivalent to the Final Order 81 FR 7451, Redesignation as Extracorporeal Circuit and Accessories For Long-term Respiratory/cardiopulmonary Failure (ECMO), February 12, 2016 for the perfusion of vessels or organs in conjunction with extracorporeal support, including Extracorporeal Membrane Oxygenation (ECMO) and Extracorporeal Life Support (ECLS).