July 15, 2021

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

Re: K201100
Trade/Device Name: Bio-Medicus Life Support Catheter and Introducer
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: June 11, 2021
Received: June 14, 2021

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,

Nicole Gillette
Assistant Director (Acting)
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)*

Device Name
Bio-Medicus Life Support™ Catheter and Introducer

Indications for Use *(Describe)*
Bio-Medicus Life Support catheters are peripheral-access catheters used to perfuse vessels or organs in conjunction with extracorporeal cardiopulmonary bypass (CPB) procedures. The catheter introducer is intended to facilitate proper insertion and placement of the appropriately-sized catheter within the vessel. Catheter models with tip lengths of 18 cm (7.09 in), 50 cm (19.7 in), or 55 cm (21.7 in) and without additional side holes may be used as either drainage or reinfusion catheters. This product is intended for use in adult and pediatric patients for up to 6 hours.

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 23, 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 Mike Green, MBA (Alternate) Sr. Regulatory Affairs Manager Phone: (763) 514-9774 Email: mike.green@medtronic.com
Trade Name: **Common Name:** **Classification Name:**	Bio-Medicus Life Support™ Catheter and Introducer Cardiopulmonary bypass vascular catheter, cannula, or tubing Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Classification:	Class II
Regulation Number:	CFR 870.4210
Product Code:	DWF
Name of Predicate Device:	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. These devices are sterile, nonpyrogenic, disposable, and intended for single use only. Do not store the product above 25°C (77°F).

Indication for Use:

Bio-Medicus Life Support catheters are peripheral-access catheters used to perfuse vessels or organs in conjunction with extracorporeal cardiopulmonary bypass (CPB) procedures. The catheter introducer is intended to facilitate proper insertion and placement of the appropriately-sized catheter within the vessel. Catheter models with tip lengths of 18 cm (7.09 in), 50 cm (19.7 in), or 55 cm (21.7 in) and without additional side holes may be used as either drainage or reinfusion catheters. This product is intended for use in adult and pediatric patients for up to 6 hours.

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:

A comparison of the Medtronic Bio-Medicus Life Support Catheters and Introducers to the predicate devices indicates the following similarities:

- Same intended use
- 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 predicate device.
- Similar materials; the only exception is the catheter body blood-contacting material which has changed from polyurethane to a siloxane-urethane co-polymer.
- Similar shelf life; the subject device has a 3-year shelf life, which is one year shorter than the predicate device (4-year shelf life).

Summary of Performance Data

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 device.

The following performance tests were conducted:

- Catheter testing
- Catheter and Introducer Testing

- Introducer Testing
- Blood trauma testing
- Packaging Testing
- Sterilization Testing
- Catheter and Introducer Life Testing
- Biocompatibility Testing
- Pressure Drop Testing

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 legally marketed predicate devices, Bio-Medicus Adult Cannulae and Introducer (K142673), Bio-Medicus Pediatric Arterial and Femoral Cannula (K143083), and Bio-Medicus Adult Cannulae and Introducer (K1804530) for the perfusion of vessels or organs in conjunction with extracorporeal cardiopulmonary bypass (CPB) procedures for up to 6 hours.