April 19, 2024

Medtronic Inc.
Kimberly Peterson
Regulatory Affairs Director
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K240534
Trade/Device Name: Bio-Medicus Life Support Catheter and Introducer
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulatory Class: Class II
Product Code: QHW, DWF
Dated: February 23, 2024
Received: February 26, 2024

Dear Kimberly Peterson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 M. Gillette -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K24053

Device Name

Bio-Medicus Life Support Catheter and Introducer

Indications for Use *(Describe)*

Cardiopulmonary Bypass (CPB):
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.

Extracorporeal Membrane Oxygenation (ECMO) and Extracorporeal Life Support (ECLS):
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.

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Date Prepared: **February 23, 2024**

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

Contact Person: Anna Wetherille
Sr. Regulatory Affairs Specialist
Medtronic Perfusion Systems
Phone: (612) 810-9450
Email: anna.wetherille@medtronic.com

Alternate Contact: Kimberly Peterson
Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: (763) 526-6751
Email: kimberly.m.peterson@medtronic.com

Device Name and Classification

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
Regulation Number: 21 CFR 870.4100
Product Code: QHW
Classification: II (with special controls)

Common Name: Extracorporeal Life Support Single Lumen Catheter
Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulation Number: 21 CFR 870.4210
Product Code: DWF
Classification: II

Predicate Device: Bio-Medicus Life Support™ Catheter and Introducer (K201057, K201100)

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 cardiopulmonary bypass (CPB), 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. Do not store the product above 25°C (77°F).

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

Indications for Use

Cardiopulmonary Bypass (CPB):

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.

Extracorporeal Membrane Oxygenation (ECMO) and Extracorporeal Life Support (ECLS):

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 Device

A comparison of the of the modified devices to the currently marketed predicate device (K201057, K201100) indicates the subject devices are substantially equivalent with the following similarities:

- Same intended use and labeling
- Same technological characteristics
- Same operating principle
- Same design features
- Same sterilization requirements, methods, and parameters
- Same shelf life
- Same packaging materials and configuration

The following device modification was made to the predicate device:

- Luer cap material formulation change (vented connector models)

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 10993-1:2018 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" (8 September 2023).
- 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.

Summary of Performance Testing

Testing has demonstrated the Bio-Medicus Life-Support Catheter and Introducers are substantially equivalent to the predicate device. The tests summarized in **Table 7-1** were conducted to demonstrate substantial equivalence of the proposed alternate luer cap (with alternate material formulation) to the predicate device.

Table 1: Summary of Changes from Predicate Device

Component	Material Change	Design Verification and Validation	Results
Luer cap	The luer cap used on vented connector models has undergone a supplier and material formulation change.	Risk-based testing and evaluations to qualify this change included product functional testing and biocompatibility assessment.	Pass

Conclusion

The information included in this submission demonstrates that the modified Medtronic Bio-Medicus Life Support Catheter and Introducer is substantially equivalent to the legally marketed predicate device, Bio-Medicus Life Support Catheter and Introducer (K201057, K201100).