April 3, 2019

Medtronic, Inc.
Huda Yusuf
Sr. Regulatory Affairs Specialist
8200 Coral Street NE
Mounds View, Minnesota 55112

Re: K190557
Trade/Device Name: Bio-Medicus Insertion Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: March 1, 2019
Received: March 5, 2019

Dear Huda Yusuf:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K190557

Device Name
Bio-Medicus Insertion Kit

Indications for Use *(Describe)*
This kit is intended for use by trained physicians only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for use 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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"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."

5.1 510(k) Summary

Date Prepared	March 1, 2019
Applicant	Medtronic, Inc Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 Establishment Registration No. 2184009
Contact Person	Ms. Huda Yusuf, M.Sc., RAC Sr. Regulatory Affairs Specialist Phone: (763) 514-9805 Email: huda.yusuf@medtronic.com Mike Green, MBA Sr. Regulatory Affairs Manager Phone: (763) 514-9774 Email: mike.green@medtronic.com
Trade Name	Bio-Medicus Insertion Kit
Common Name	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification Name	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Classification	Class II, 21 CFR 870.4210
Product Code	DWF
Name of Predicate Device	Bio-Medicus Insertion Kit (K150567, predicate)

Device Description

The Bio-Medicus Insertion Kits are used during cardiopulmonary bypass procedures. The product contains the necessary components to achieve insertion of the Adult and Pediatric Bio-Medicus Femoral Cannulae and Introducer. Each kit is comprised of:

- Seldinger needle
- Scalpel blade
- Catheter tipped syringe
- Stepped dilators
- Guidewire

The Bio-Medicus Insertion Kits are all supplied sterile, and non-pyrogenic and are for single use only.

Indications for Use

This kit is intended for use by trained physicians only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for use for up to 6 hours.

Contraindication

Alone, this kit is not a medical treatment device. Selection of patients as candidates for such procedures is the physician's responsibility. The outcome is dependent on many variables, including patient pathology, surgical procedure, and perfusion procedures. These devices are not intended for use except as indicated above. Do not use the kit if the patient has severe peripheral atherosclerosis or severe arterial dissection.

Comparison to Predicate Devices

A comparison of the of the Medtronic Bio-Medicus Insertion Kit to the predicate device indicates the following similarities:

- Same intended use
- Same operating principle
- Same design features
  - Except for the replacement of the current dilators with dilators supplied by Medcomp
- Same device and packaging materials
- Same sterilization requirements
- Same shelf life
- Same technological characteristics as shown in the following table:

Category	Proposal Device Bio-Medicus Insertion Kit	Predicate Device Bio-Medicus Insertion Kit
510(k)	K190557	K150567
Models	96551 96552 96553	96551 96552 96553
Kit Configuration	Model 96551 • (1) Stepped Dilator – 8/10 FR • (1) Stepped Dilator – 12/14 FR • (1) Stepped Dilator – 16/18 FR • (1) Guidewire, 0.038-in (0.965-mm) x 180-cm (70.87-in) • (1) Seldinger needle – 18 ga • (1) Scalpel blade – #11 • (1) 10 cc Syringe Model 96552 • (1) Stepped Dilator – 8/10 FR • (1) Stepped Dilator – 12/14 FR • (1) Stepped Dilator – 16/18 FR • (1) Guidewire, 0.038-in (0.965-mm) x 100-cm (39.37-in) • (1) Seldinger needle – 18 ga • (1) Scalpel blade – #11 • (1) 10 cc Syringe Model 96553 • (1) Stepped Dilator – 8/10 FR • (1) Stepped Dilator – 12/14 FR • (1) Guidewire, 0.025-in (0.635-mm) x 60-cm (23.62-in)	Model 96551 • (1) Stepped dilator – 8/10 FR • (1) Stepped dilator – 12/14 FR • (1) Stepped dilator – 16/18 FR • (1) Guidewire, 0.038-in (0.965-mm) x 180-cm (70.87-in) • (1) Seldinger needle – 18 ga • (1) Scalpel blade – #11 • (1) 10 cc Syringe Model 96552 • (1) Stepped dilator – 8/10 FR • (1) Stepped dilator – 12/14 FR • (1) Stepped dilator – 16/18 FR • (1) Guidewire, 0.038-in (0.965-mm) x 100-cm (39.37-in) • (1) Seldinger needle – 18 ga • (1) Scalpel blade – #11 • (1) 10 cc Syringe Model 96553 • (1) Stepped dilator – 8/10 FR • (1) Stepped dilator – 12/14 FR • (1) Guidewire, 0.025-in (0.635-mm) x 60-cm (23.62-in)

Category	Proposal Device Bio-Medicus Insertion Kit	Predicate Device Bio-Medicus Insertion Kit
	• (1) Seldinger needle – 18 ga • (1) Scalpel blade – #11 • (1) 10 cc Syringe Note: all stepped dilators are supplied by Medcomp	• (1) Seldinger needle – 18 ga • (1) Scalpel blade – #11 • (1) 10 cc Syringe

Conclusion

In conclusion, the information included in this submission demonstrates that the Bio-Medicus Insertion Kits, with the replacement of the current dilators with dilators supplied by Medcomp, are substantially equivalent to the legally marketed predicate devices.