March 22, 2018

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

Re: K180453
Trade/Device Name: Bio-Medicus Adult Cannulae 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: February 16, 2018
Received: February 20, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Nicole G. Ibrahim -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)*

K180453

Device Name
Bio-Medicus Adult Cannulae and Introducer

Indications for Use *(Describe)*

These devices are to be used by a trained physician only. Cannulae are used to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of the appropriately-sized cannula within the vessel for cardiopulmonary bypass. The Bio-Medicus™ cannula (18-cm [7.09-in] tip length models) may be used in either the femoral position as an arterial delivery cannula or in the jugular position as venous return cannula. This product is intended for use 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.

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 of Safety and Effectiveness

Date Prepared	February 16, 2018
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 Fax: (763) 367-8147 Email: huda.yusuf@medtronic.com Mike Green, MBA Regulatory Affairs Manager Phone: (763) 514-9774 Fax: (763) 367-8147 Email: mike.green@medtronic.com
Trade Name	Bio-Medicus™ Adult Cannulae and Introducer
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™ Adult Cannulae and Introducer (K142673)

Device Description

The Bio-Medicus™ Adult Cannulae and Introducer is intended to be used to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of the appropriate sized cannula within the vessel for cardiopulmonary bypass.

The Bio-Medicus™ Adult Cannulae and Introducer set consists of adult arterial and venous cannulae and introducer. This submission will focus on the adult venous cannulae only. The adult venous cannulae are all supplied sterile, and non-pyrogenic and are for single use only.

The adult venous cannula consists of:

- Polyurethane cannula with stainless steel wire-wound multi-port body
    - Non-vented 3/8-in connector
    - The overall length of the cannulae is 25.6-in and 30-in
- Insertion marks that aid in positioning the cannula
- Repositionable suture ring that is radiopaque

The one-piece non-phthalate PVC introducers included with these cannulae have an elongated taper for dilation over a longer distance.

The Bio-Medicus™ Adult Cannulae and Introducer package contains a securement clip which can be used near the insertion site for securement of the cannula body which aides in securement as well as an aide for physician organization. The large venous models (23-25 Fr) also contain a 3/8-in x ½-in tubing adapter with an attached length of 3/8-in tubing to allow connection to a ½-in cardio pulmonary bypass circuit.

This new Bio-Medicus™ Adult Cannulae and Introducer set consists of increased number of drainage side holes along the insertable length and the increase of depth markings from every 10cm to every 5cm to further aid in positioning of the cannula. The change is taking place on the 15 French (F) through 25 F adult venous Bio-Medicus cannulae.

Intended Use

These devices are to be used by a trained physician only. Cannulae are used to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of the appropriately-sized cannula within the vessel for cardiopulmonary bypass. The Bio-Medicus™ cannula (18-cm [7.09-in] tip length models) may be used in either the femoral position as an arterial delivery cannula or in the jugular position as venous return cannula. This product is intended for use up to 6 hours.

Contraindications

Alone, the cannula and introducer are not medical treatment devices. The cannula introducer is only to be used with the appropriately-sized Bio-Medicus cannula. These devices are not intended for use, except as indicated above. Do not use if the patient has severe peripheral atherosclerosis or severe arterial dissection.

Comparison to Predicate Devices

A comparison of the Medtronic Bio-Medicus™ Adult Cannulae and Introducer to the predicate device indicates the subject devices are substantially equivalent with the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
  - except for increased number of drainage side holes along the insertable length and
  - the increase of depth markings from every 10cm to every 5cm to further aid in positioning of the cannula
  - the addition of a single marking which is 5cm from the proximal set of holes to further aid the positioning of the cannula
- Same device and packaging materials
- Same sterilization requirements
- Same shelf life

Summary of Performance Data

Bench testing was used to verify the performance characteristics of these devices. Clinical testing was not required to establish substantial equivalence.

The following tests were conducted:

- Blood Trauma Testing
- Bioburden Testing
- Pressure Drop Testing
- Cannula Testing-Kink During Perfusion
- Depth Marking Presence

Conclusion

In conclusion, the information included in this submission demonstrates that the Bio-Medicus™ Adult Cannulae and Introducer, with the changes made to them, are substantially equivalent to the legally marketed predicate devices.