DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 27 2015

Medtronic, Inc
Bruce Backlund
Principal Regulatory Affairs Specialist
8200 Coral St Ne
Mounds View, Minnesota 55112

Re: K143083
Trade/Device Name: Bio-Medicus Pediatric Cannulae and Introducers
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: February 9, 2015
Received: February 11, 2015

Dear Mr. Backlund,

This letter corrects our substantially equivalent letter of March 25, 2015.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143083

Device Name
Bio-Medicus Pediatric Cannulae and Introducers

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. These products are 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary of Safety and Effectiveness

Date Prepared:	**October 23, 2014**
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 **Establish Registration Number:** 2184009
Contact Person:	Bruce Backlund Principal Regulatory Affairs Specialist Phone: (763) 526-2357 Fax: (763) 367-8361 E-mail:bruce.j.backlund@medtronic.com
Trade Name:	Bio-Medicus™ Pediatric Cannulae and Introducers
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 Devices:	Bio-Medicus™ Cannula-Tubing (K872033) DLP Pediatric™ One-Piece Arterial Cannulae (K024069)

Device Description:

The pediatric venous cannulae consist of a polyurethane wirewound body with a multi-port distal tip. All pediatric venous cannulae come with a non-vented 1/4-in connector. The one-piece non-phthalate PVC blunt and guidewire style introducers and included with these cannulae have an elongated taper for dilation over a longer distance.

The pediatric arterial cannulae consist of a polyurethane wirewound body and distal tip. All of the pediatric arterial cannulae come with a non-vented 1/4-in connector. The one-piece non-

phthalate PVC blunt and guidewire introducers included with these cannulae have an elongated taper for dilation over a longer distance.

Sterile, nonpyrogenic disposable, single use only

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. These products are intended for use up to 6 hours.

Contraindications:

Alone, the cannula and introducer are not medical treatment devices. The introducer is to be used only with the appropriately-sized Bio-Medicus™ cannula. These devices are not intended for use except as indicated above.

Comparison to Predicate Devices:

A comparison of the Medtronic Bio-Medicus Pediatric Arterial and Venous Cannulae to the predicate devices indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Similar design features, exceptions include improved transition between the introducer body and cannula tip to increase ease of cannula insertion, and an added radiopaque suture ring.
- Similar materials, exceptions include the introducer material which has changed from Polyethylene to Polyvinyl Chloride (PVC), connector material from Polycarbonate to PVC and hemostasis cap material from Styrene to Silicone.
- Same shelf life

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device. Animal testing was also completed to establish substantial equivalence with the predicate devices.

The following performance tests were conducted and passed:

- Blood Trauma Testing
- Sterilization Testing
- Packaging Testing
- Pressure Drop Testing
- Cannula Shelf Life Testing
- Cannula and Introducer Performance Testing
- Cannula Testing
- Introducer Testing
- Securement Clip Testing with Cannula and Introducer
- Biocompatibility Testing (all blood contacting surfaces)
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Toxicity
  - Pyrogenicity
  - Genotoxicity
  - Hemocompibility
  - Subacute Toxicity

Biocompatibility testing was performed in accordance with ISO 10993-1 Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process. Performance and biological tests confirm that the Medtronic Bio-Medicus Pediatric Arterial and Venous Cannulae product met pre-determined acceptance criteria and is substantially equivalent to the predicate device.

Conclusion:

The primary predicate device, Bio-Medicus™ Cannula-Tubing was used to compare the fundamental technological characteristics of the proposed Bio-Medicus Pediatric Arterial and Venous Cannula and Introducer. When comparative testing was completed, the proposed Bio-Medicus Pediatric Cannulae and Introducer performed as well or better than the legally marketed devices.

The data included in this submission is sufficient to provide reasonable assurance that the Bio-Medicus Pediatric Arterial and Venous Cannulae and Introducers are substantially equivalent to the legally marketed predicate Bio-Medicus Cannula-Tubing (K872033) device.