



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

January 15, 2016

Medtronic, Inc.
Jennifer Tang
Principal Regulatory Affairs Specialist
8200 Coral Sea Street Ne
Mounds View, Minnesota 55112

Re: K153598

Trade/Device Name: Bio-Medicus™ Adult Cannula Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 15, 2015
Received: December 16, 2015

Dear Jennifer Tang:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number (if known): K153598

Device Name: Bio-Medicus™ Adult Cannula Kit

Indications for 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™ cannulae (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 a venous return cannula. This product is intended for use up to 6 hours.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2. 510(k) Summary

Date Prepared: December 15, 2015

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

Contact Person: Jennifer Tang
Principal Regulatory Affairs Specialist
Medtronic Perfusion Systems
Phone: (763) 526-6758
Fax: (763) 367-8360
Email: Jennifer.tang@medtronic.com

Alternate Contact:

Susan C. Fidler
Sr. Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: (763) 514-9839
Fax: (763) 367-8360
Email: susan.c.fidler@medtronic.com

Common Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing.

Proprietary Name: Bio-Medicus™ Adult Cannula Kit

Classification: Classification: Class II
Panel: Cardiovascular
Regulation: 21 CFR 870.4210
Product Code: DWF

Predicate Device: Medtronic Bio-Medicus™ Insertion Kit (K150567) and Medtronic Bio-Medicus™ Cannula Adult Cannula and Introducer (K142673)

Device Description

This kit is a combination of the following two sets of devices:

- Bio-Medicus Adult Cannula and Introducer, cleared on November 18, 2014 (K142673)
- Bio-Medicus Insertion Kit, cleared on April 9, 2015 (K150567)

The Bio-Medicus Adult Cannula and Introducer is designed to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal equipment and is designed for periods of up to six hours of use.

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 a venous return cannula.

Bio-Medicus™ Insertion Kits contains the necessary components to achieve insertion of a Bio-Medicus™ cannula and introducer. The included items are: a Seldinger needle, a guidewire, a scalpel blade, stepped dilators, and a catheter tip syringe.

Indications for 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™ cannulae (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 a venous return cannula. This product is intended for use up to 6 hours.

Comparison to Predicate Device

A comparison of the proposed product to the currently marketed Medtronic Bio-Medicus Adult Cannula and Introducer (K142673) and Medtronic Bio-Medicus™ Cannula Adult Cannula and Introducer (K142673) indicates the following similarities:

- Same intended use
- Same operating principle
- Same fundamental technological characteristics
- Same materials
- Same sterilization requirements
- Same shelf life

A detailed, technological characteristics comparison is provided in section 12 of this submission.

Conclusion

Compared to the predicate devices, the fundamental scientific technology, operating principles, design features, intended use, and shelf life are unchanged. As such, it has been demonstrated that Bio-Medicus Adult Cannula Kit described in this submission is substantially equivalent to the predicate devices.