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

August 15, 2014

Kevin T. Lam
Senior Regulatory Affairs Specialist
Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Re: K141951
Trade/Device Name: DLP® Silicone Coronary Artery Ostial Cannulae;
Model Numbers 30315, 30317, and 30320
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: II
Product Code: DWF
Dated: July 17, 2014
Received: July 18, 2014

Dear Mr. Lam:

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" (21CFR 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 Zuckerman, MD
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)*
K141951

Device Name
DLP Silicone Coronary Artery Ostial Cannulae

Indications for Use *(Describe)*
These Cannulae are intended for use in conjunction with cardiopulmonary bypass surgery up to six hours or less for delivery of cardioplegia solutions directly to the coronary arteries.

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.

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."

K141951

510(k) Summary

Date Prepared: July 17, 2014

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

Contact Person: Kevin T. Lam
Senior Regulatory Affairs Specialist
Medtronic Perfusion Systems
Phone: 763.526.2360
Fax: 763.367.8360
Email: *kevin.t.lam@medtronic.com*

Alternate Contact:
Susan Fidler
Senior Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: 763.514.9839
Fax: 763.367.8360
Email: *susan.c.fidler@medtronic.com*

Device Name and Classification

Trade Name:	DLP® Silicone Coronary Artery Ostial Cannulae Models: 30315, 30317, and 30320
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Product Classification:	Class II

Predicate Devices

K131269	DLP® Silicone Coronary Artery Ostial Cannulae

Device Description
The DLP® Silicone Coronary Artery Ostial Cannulae feature a soft bulb beveled tip with a silicone body. The Cannulae terminate with a locking female luer fitting. The Cannulae are nonpyrogenic, single use, and sterile.

Indications for Use
These Cannulae are intended for use in conjunction with cardiopulmonary bypass surgery up to six hours or less for delivery of cardioplegia solutions directly to the coronary arteries.

Comparison to Predicate Devices
A comparison of the modified product to the currently marketed predicate products (K131269) indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials (Silicone and Polypropylene)
- Same shelf life
- Same manufacturing process

Summary of Performance Data

Testing has demonstrated that the DLP® Silicone Coronary Artery Ostial Cannulae are substantially equivalent to the predicate.

The following performance tests were conducted:

Component	Base Material Changes	Verification/Validation	Results
Barbed Female Luer	Current: Polypropylene Proposed: Polypropylene	Hub tested for Tensile Pull-Off Force	Pass
		Dimensional analysis	Pass
		Biocompatibility	Pass
Silicone adhesive for ink printing	From: Silicone To: Silicone	Rub off test	Pass
		Biocompatibility	Pass

Conclusion
Medtronic has demonstrated that the material changes made to the DLP® Silicone Coronary Artery Ostial Cannulae presented in this submission resulted in a substantially equivalent device

because the base material types, fundamental scientific principle, operating principle, design features, and intended use are unchanged from the predicate devices.