510(k) Summary

MAR 2 7 2013

Date Prepared: December 6, 2012

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Device Name and Classification

Trade Name:	DLP® Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Product Classification:	Class II

Predicate Devices

K901074	Retrograde Coronary Sinus Perfusion Cannula
K030696	Retrograde Coronary Sinus Perfusion Cannula without Pressure Monitoring Lumen

Device Description
The cannulae consist of either a Polyvinyl Chloride (PVC) body or a silicone wirewound kink-resistant body with auto-inflate cuff. The cannula is used for direct cannulation within the coronary sinus to deliver cardioplegia solution during cardiopulmonary bypass surgery. The back of the cannula body terminates in a locking female luer. These cannulae utilize a guidewire or solid stylet to facilitate trans-atrial introduction. The cannulae are nonpyrogenic, single use, and sterile.

Indications for Use
This device is intended for use during cardiopulmonary bypass surgery up to six hours or less, for the delivery of cardioplegia retrogradely through the coronary sinus.

Comparison to Predicate Devices
A comparison of the modified product to the currently marketed predicate products (K901074 and K030696) indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials
- Same shelf life

Summary of Design Verification Testing
The DLP® Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff product family added an additional French size option, which was tested through the design verification process. The samples were subjected to a kink test, a simulated use test, functional tests of the cannula (bond joint tensile test and leak testing of all bonded connections), and functional tests of the introducer (twist test and tensile test). All samples passed the verification testing.

Summary of Performance Testing
The DLP® Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff product family added an additional cuff style, which was performance tested. The samples were subjected to retention force testing to ensure acceptable retention within the coronary sinus. All samples passed the verification testing.

Conclusion
Medtronic has demonstrated that the modifications made to the DLP® Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff product family described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 27, 2013

Medtronic, Inc.
C/O Chelsea Pioske
8200 Coral Sea Street NE
Mounds View, MN 55433

Re: K123762
Trade/Device Name: DLP Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: March 7, 2013
Received: March 8, 2013

Dear Ms. Pioske:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.htmfor 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 Small Manufacturers, International and Consumer Assistance 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,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K123762

Device Name: DLP® Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff

Indications for Use:

This device is intended for use during cardiopulmonary bypass surgery up to six hours or less, for the delivery of cardioplegia retrogradely through the coronary sinus.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner

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