

510(k) Summary

OCT 31 2013

Date Prepared: September 20, 2013
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Device Name and Classification

Trade Name: DLP[®] Retrograde Coronary Sinus Perfusion Cannula Without Pressure Monitoring Line (also known as DLP[®] Retrograde Coronary Sinus Perfusion Cannula Without Pressure Monitoring Lumen)
Models: 94115NPL, 94535NPL, 94725NPL
Common Name: Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulation Number: 21 CFR 870.4210
Product Code: DWF
Product Classification: Class II

Predicate Devices

K030696 Retrograde Coronary Sinus Perfusion Cannula with no Pressure Monitoring Line

Device Description

The DLP[®] Retrograde Coronary Sinus Perfusion Cannulae Without Pressure Monitoring Line devices consist of a silicone or extruded PVC body. The silicone cannulae consist of a kink resistant wirewound body and a beveled tip with two side holes. A smooth manual inflating balloon is located at the distal end of the wirewound body and has an inflation assembly at the proximal end of the cannula that contains a female luer and a one-way valve. The PVC cannula consists of an extruded body with a multi-port tip and a smooth pre-formed auto-inflating balloon. Both silicone and PVC cannulae terminate with a female luer on the proximal end. These devices are offered with either a guidewire stylet or a solid stylet to help position the cannula. The cannula are sterile, non-pyrogenic, disposable, and for single use only.

Indications for Use

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

Comparison to Predicate Devices

A comparison of the modified product to the currently marketed predicate products indicates the following similarities:

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

Summary of Biocompatibility Testing for Previously Implemented Changes

The DLP[®] Retrograde Coronary Sinus Perfusion Cannulae Without Pressure Monitoring Line devices have changed the the luers and the ink material since the predicate was first cleared. Additionally, the concentration of a chemical within a manufacturing process aid was decreased. The change to blue ink was cleared previously in K120988 and K123762. A summary of the biocompatibility tests performed for the changes to the luer material and manufacturing process material are summarized below.

Test	Luer Material Change Biocompatibility Test Result	Manufacturing Process Material Change (Worst-Case) Biocompatibility Test Result
Cytotoxicity	PASS	PASS
Sensitization assay	PASS	PASS
Intracutaneous reactivity study	PASS	PASS
Systemic toxicity (acute) • Acute systemic toxicity study	PASS	PASS
Systemic toxicity (acute) • Pyrogen	PASS	PASS
Genotoxicity	PASS	PASS
Hemocompatibility	PASS	PASS

Summary of Bench Testing for Previously Implemented Changes

The DLP® Retrograde Coronary Sinus Perfusion Cannulae Without Pressure Monitoring Line devices changed the material of non-blood-contacting components used in the check valve. Function (pressure integrity) testing was completed to show that the component assembly would continue meeting the current specification (thus, demonstrating that the cannula would continue to meet performance specifications). Test results met the specified criteria.

Conclusion

Medtronic has demonstrated that the modifications made to the DLP® Retrograde Coronary Sinus Perfusion Cannulae Without Pressure Monitoring Line devices described in this submission results in a substantially equivalent device because the fundamental scientific principle, operating principle, design features, and overall intended use are unchanged from the predicate device.



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

October 31, 2013

Medtronic Inc.
c/o Chelsea Pioske
Associate Regulatory Affairs Specialist
Medtronic Perfusion Systems
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K132995
Trade/Device Name: DLP® Retrograde Coronary Sinus Perfusion Cannula Without Pressure Monitoring Lumen
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWF
Dated: September 20, 2013
Received: September 24, 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 contact 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>. 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 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,

Bram D. Zuckerman -S

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): K132995

Device Name: DLP® Retrograde Coronary Sinus Perfusion Cannula Without Pressure Monitoring Lumen

Indications for Use:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Bram D. Zuckerman -S
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