October 19, 2018

Medtronic, Inc.
Linda Julia Davila
Regulatory Affairs Specialist
8200 Coral Street NE
Mounds View, Minnesota 55125

Re: K182586
Trade/Device Name: DLP™ Aortic Root Cannula (Model 23009), DLP™ Aortic Root Cannula with Vent Line (Model 24009), DLP™ Cardioplegia Adapter with Pressure Port (Model 15004), DLP™ Pressure Monitoring Extension Line Adapter (Models 25009 and 25010)
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 19, 2018
Received: September 20, 2018

Dear Linda Julia Davila:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel -S

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K182586

Device Name
DLP Aortic Root Cannula (Model 23009); DLP Aortic Root Cannula with Vent Line (Model 24009); DLP Cardioplegia Adapter with Pressure Port (Model 15004); DLP Pressure Monitoring Extension Line Adapter (Models 25009 and 25010)

Indications for Use *(Describe)*
The DLP Aortic Root Cannula (Model 23009) is intended for short term use (six hours or less) in conjunction with cardiopulmonary bypass surgery for delivering cardioplegia solutions. The cannula may also be used to aspirate air from the aorta at the conclusion of the bypass procedure. The Model 23009 cannula may also be used to monitor pressure in the aorta.

The DLP Aortic Root Cannula with Vent Line (Model 24009) is intended for use during cardiopulmonary bypass for delivering cardioplegia solutions and venting of the left heart for up to 6 hours. The cannula may be used to aspirate air from the aorta at the conclusion of the bypass procedure. The Model 24009 cannula may also be used to monitor pressure in the aorta.

The DLP Cardioplegia Adapter with Pressure Port (Model 15004) is intended for use in conjunction with the delivery of cardioplegia solution and to provide access for pressure monitoring for up to 6 hours.

The DLP Pressure Monitoring Extension Line Adapter (Models 25009 and 25010) is intended for extending the pressure line in order to reach the pressure monitoring unit during cardiopulmonary bypass surgery up to 6 hours or less.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 5.0 510(k) Summary

## 510(k) Summary

| | |
|---|---|
| Date Prepared: | Sept 18, 2018 |
| Submitter: | Medtronic, Inc.<br>Medtronic Perfusion Systems<br>7611 Northland Drive<br>Minneapolis, MN 55428<br>Establishment Registration Number: 2184009 |
| Contact Person: | Linda L Julia Davila<br>Regulatory Affairs Specialist<br>Medtronic Perfusion Systems<br>Phone: 763.526.9737<br>Email: *linda.l.juliadavila@medtronic.com* |
| Alternate Contact: | Mike Green<br>Senior Regulatory Affairs Manager Medtronic Perfusion Systems<br>Phone: 763.514.9774<br>Email: *mike.green@medtronic.com* |

Device Name and Classification

| | |
|---|---|
| Trade Name: | DLP™ Aortic Root Cannula (Model 23009)<br>DLP™ Aortic Root Cannula with Vent Line (Model 24009)<br>DLP™ Cardioplegia Adapter with Pressure Port (Model 15004)<br>DLP™ Pressure Monitoring Extension Line Adapter (Model 25009 and 25010) |
| Common Name: | Cardiopulmonary bypass vascular catheter, cannula, or tubing |
| Regulation Number: | 21 CFR 870.4210 |
| Product Code: | DWF |
| Product Classification: | Class II |

### Name of Predicate Device

| | |
|---|---|
| K831591 | DLP™ Aortic Root Cannula with Integral Pressure Monitoring Line and Extension Set |

## Device Description

The proposed modification will affect the DLP Aortic Root Cannula with Integral Pressure Monitoring Line and Extension Set product family. A description of these devices follows below.

Model 23009

The DLP Aortic Root Cannula consists of flexible tubing permanently attached to both the inlet and tip. The inlet fitting is a female luer fitting. The introducer is packaged within the cannula body.

Model 24009

The DLP Aortic Root Cannula with Vent Line consists of a soft, flexible, thin-wall tip permanently attached to a flexible Y-type adapter. Flexible tubing is permanently attached to both the inlet and vent port of the Y-type adapter. The cannula inlet fitting is a female luer and the vent port fitting (outlet) is a slip-on connector for 0.48 cm (3/16 in) to 0.64 cm (1/4 in) Inner Diameter (I.D.) tubing. The introducer is packaged within the cannula body.

Model 15004

The DLP Cardioplegia Adapter with Pressure Port consists of flexible tubing, luer connections, and a latex-free rubber septum. The end that terminates with a male luer connector connects to the cardioplegia cannula and the other end connects to the cardioplegia administration set. A latex-free rubber septum provides access for a pressure monitoring needle near the connection to the cardioplegia cannula.

Model 25009 and 25010

The DLP Pressure Monitoring Extension Line Adapter is 1.8 m (6 ft) in length with a locking male luer fitting on one end, and either a locking female luer fitting (Model 25009) or a locking male luer fitting (Model 25010) on the other end.

All are provided sterile, nonpyrogenic, and for single use.

## Indications for Use

The DLP Aortic Root Cannula (Model 23009) is intended for short term use (six hours or less) in conjunction with cardiopulmonary bypass surgery for delivering cardioplegia solutions. The cannula may also be used to aspirate air from the aorta at the conclusion of the bypass procedure. The Model 23009 cannula may also be used to monitor pressure in the aorta.

The DLP Aortic Root Cannula with Vent Line (Model 24009) is intended for use during cardiopulmonary bypass for delivering cardioplegia solutions and venting of the left heart for up to 6 hours. The cannula may be used to aspirate air from the aorta at the conclusion of the bypass procedure. The Model 24009 cannula may also be used to monitor pressure in the aorta.

The DLP Cardioplegia Adapter with Pressure Port (Model 15004) is intended for use in conjunction with the delivery of cardioplegia solution and to provide access for pressure monitoring for up to 6 hours.

The DLP Pressure Monitoring Extension Line Adapter (Models 25009 and 25010) is intended for extending the pressure line in order to reach the pressure monitoring unit during cardiopulmonary bypass surgery up to 6 hours or less.

## Comparison to Predicate Devices

A comparison of the modified product to the currently marketed predicate products (K831591) indicates the following similarities:

- Intended use
- Technological characteristics
- Operating principle
- Design features
- Base materials
- Shelf life

The details of the changes for the DLP Aortic Root Cannula and Adapters are described in Section 12.0 of this 510(k) and the proposed modifications are similar to the predicate device.

## Conclusion

Medtronic has demonstrated that the modifications made to the DLP Aortic Root Cannula with Integral Pressure Monitoring Line and Extension Set product family described in this submission result in a substantially equivalent[1] device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate devices.

[1] The term 'substantially equivalent' as used herein is intended to be a determination of substantial equivalency under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters." (Federal Register, Vol. 42, No. 163, Aug. 23, 1977, page 42525 and 42529).