



December 7, 2023

Medtronic, Inc.
Stephen Beier
Principal Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K231206

Trade/Device Name: DLP Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, 30320
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 27, 2023
Received: April 27, 2023

Dear Stephen Beier:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette

Assistant Director

DHT2B: Division of Circulatory Support,
Structural and Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K231206

Device Name

DLP Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320

Indications for Use (Describe)

The DLP Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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
PRASStaff@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."

510(k) Summary

Date Prepared: December 6, 2023

Applicant: Medtronic, Inc
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration No. 2184009

Contact Person: Stephen Beier
Principal Regulatory Affairs Specialist
Phone: (763) 526-6751
Fax: (763) 367-8361
Email: stephen.beier2@medtronic.com

Alternate Contact: Diane Howell
Regulatory Affairs Manager
Phone: (651) 214-2693
Email: diane.d.howell@medtronic.com

Device Name and Classification

Trade Names: 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

Classification: Class II

Predicate Device

K141951 DLP™ Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, 30320

Device Description

The DLP™ Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320 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

The DLP™ Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320 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 of the modified devices to the currently marketed predicate device (K141951) indicates the subject devices are substantially equivalent¹ with the following similarities:

- Same intended use and labeling
- Same technological characteristics
- Same operating principle
- Same design features
- Same sterilization requirements, methods, and parameters
- Same 3-year shelf life
- Same packaging materials and configuration

The following device modification was made to the predicate device:

- Adhesive material formulation change

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).

Table 5-1: Summary of Changes from Predicate Device

Component	Material Change	Design Verification and Validation	Results
Adhesive used to encapsulate the bulb tip of the DLP™ Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320	The adhesive used in the design of the Cannulae has undergone a raw material formulation change.	Risk-based testing and evaluations to qualify this change included product functional testing and a biocompatibility assessment.	All results pass

Summary of Performance Data

Testing has demonstrated that the DLP™ Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320 are substantially equivalent to the predicate device. Table 5-1 defines the material change that has been made to the predicate device and the design verification and validation activities that were completed to evaluate the updated adhesive formulation.

Conclusion

Medtronic has demonstrated that the modified DLP™ Silicone Coronary Artery Ostial Cannulae, Models 30315, 30317, and 30320 are substantially equivalent to the predicate device based on the fundamental scientific principles, operating principles, design features and intended use being unchanged from the predicate device.