May 4, 2023
Medtronic, Inc.
Stephen Beier
Principal Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K230960
Trade/Device Name: DLP™ Silicone Coronary Artery Ostial Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 4, 2023
Received: April 5, 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 (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/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 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 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,

Kathleen M. Grunder -S

Kathleen Grunder
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230960

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)

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.

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510(k) Summary

Date Prepared:	April 04, 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

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 of the modified devices to the currently marketed predicate device (K141951) indicates the subject devices are substantially equivalent[11] with the following similarities:

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

The following device modifications were made to the predicate device:

- Packaging material 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 Changes	Design Verification and Validation	Results
Form-fill-seal (FFS) pouch material	The pouch material used in the FFS packaging process has undergone a change from a Surlyn film pouch to a Nylon film pouch.	Risk-based testing and evaluations to qualify this change included product functional testing, a biocompatibility assessment and completion of a product shelf life study.	All results pass

Summary of Performance Data

Testing has demonstrated that the DLP™ Silicone Coronary Artery Ostial Cannulae are substantially equivalent to their predicate devices. Table 5-1 describes the change that has been made to the predicate devices' packaging and the design verification and validation activities that were completed to evaluate the new packaging material.

Conclusion

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