October 29, 2026

Medtronic, Inc.
Vinoda Palanisamy
Senior Regulatory Affairs Specialist
7611 Northland Dr. N
Brooklyn Park, Minnesota 55428

Re: K263596
Trade/Device Name: DLP™ Coronary 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: September 30, 2026
Received: September 30, 2026

Dear Vinoda Palanisamy:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263596

Please provide the device trade name(s).

DLP™ Coronary Ostial Cannulae

Please provide your Indications for Use below.

The device is indicated for conditions requiring CPB procedures up to 6 hours in duration for delivery of cardioplegia solutions directly to the coronary arteries.

Please select the types of uses.

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary of Safety and Effectiveness

Date Prepared:	September 17, 2026
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 Establish Registration Number: 2184009
Contact Person:	Vinoda Palanisamy Senior Regulatory Affairs Specialist Email: vinoda.palanisamy@medtronic.com Megan Smith, Senior Regulatory Affairs Specialist, Email:megan.smith@medtronic.com
Trade Name/ Device Name:	DLP™ Coronary Ostial Cannulae- (30315, 30317, 30320) 30010, 30012, 30014, 30050, 30055, 30110, 30112, 30114, 30155, 30212, 30255)
Regulation Description:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification:	Class II
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Predicate Device:	DLP™ Silicone Coronary Ostial Cannulae (K231206) DLP™ Coronary Ostial Cannulae (K131269)

Device Description:

The DLP™ Coronary Ostial Cannulae product family consists of sterile, nonpyrogenic, single-use disposable cardioplegia delivery cannulae intended for delivery of cardioplegia solutions directly to the coronary arteries via the coronary ostia during cardiopulmonary bypass (CPB) procedures.

The product family includes:

- DLP™ Coronary Ostial Cannulae
- DLP™ High Flow Coronary Ostial Cannulae
- DLP™ Silicone Coronary Ostial Cannulae

The devices incorporate a variety of tip styles, body configurations, and sizes to support clinician preference and surgical application while maintaining the same intended use and operating principles.

Indications for Use:

The device is indicated for conditions requiring CPB procedures up to 6 hours in duration for delivery of cardioplegia solutions directly to the coronary arteries.

Substantial Equivalence:

The subject DLP™ Coronary Ostial Cannulae, DLP™ High Flow Coronary Ostial Cannulae, and DLP™ Silicone Coronary Ostial Cannulae have the same intended use, fundamental scientific technology, principles of operation, anatomical site of use, sterilization method, shelf life, and packaging configuration as the predicate devices. The proposed modifications are limited to labeling revisions applicable to all device models. Risk assessments demonstrated that the modifications do not adversely affect safety, performance, or effectiveness. Therefore, the subject devices are substantially equivalent to the predicate devices

Comparison to Predicate:

The subject devices have the same:

- Intended use
- Technological Characteristics
- Principles of operation
- Anatomical site of use
- Sterilization method
- Shelf life
- Packaging configuration
- Overall device design

as predicate devices.

Differences between the subject and predicate devices are limited to labeling revisions applicable to all device models. These modifications do not affect the intended use, technological characteristics, or operating principles of the devices.

Labeling Revisions

Labeling revisions were implemented to improve alignment with:

- Current regulatory requirements
- Recognized consensus standards
- Risk management documentation
- Global labeling harmonization initiatives

The updates include reorganization and clarification of existing safety information, addition of regulatory disclosures and symbols, hazardous substance disclosures where applicable, and editorial revisions intended to improve labeling clarity, consistency, and harmonization across global markets.

The labeling revisions do not alter the device's intended use, indications for use, technological characteristics, design, performance specifications, or principles of operation. The changes are limited to labeling and associated risk management documentation updates and do not impact the overall benefit-risk profile of the device.

Conclusion:

The subject DLP™ Coronary Ostial Cannulae, DLP™ High Flow Coronary Ostial Cannulae, and DLP™ Silicone Coronary Ostial Cannulae have the same intended use, operating principles, and fundamental scientific technology as the cited predicate devices.

Risk evaluations demonstrate that the modifications do not adversely affect device safety, performance, or effectiveness.

Therefore, the subject devices do not raise different questions of safety and effectiveness and are substantially equivalent to the predicate devices K131269 and K231206.