October 23, 2026

Medtronic
Lara Ouillette
Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K261792
Trade/Device Name: DLP PVC Left Heart Vent; DLP Malleable PVC Left Heart Vent; DLP Silicone Left Heart Vent
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 25, 2026
Received: September 25, 2026

Dear Lara Ouillette:

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.	K261792

Please provide the device trade name(s).

DLP PVC Left Heart Vent;
DLP Malleable PVC Left Heart Vent;
DLP Silicone Left Heart Vent

Please provide your Indications for Use below.

This catheter is indicated for use in venting the left heart during cardiopulmonary bypass (CPB) surgery up to 6 hours.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary of Safety and Effectiveness

Date Prepared:	October 23, 2026
Submission Number:	K261792
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428
Establish Registration Number:	2184009
Contact Person:	Lara Ouillette Regulatory Affairs Specialist Phone: 517-304-2385 Email: lara.ouillette@medtronic.com Diane Howell (Alternate) Regulatory Affairs Manager Phone: 612-597-5297 Email: diane.d.howell@medtronic.com
Trade Name:	DLP Malleable PVC Left Heart Vent DLP PVC Left Heart Vent DLP Silicone Left Heart Vent
Common Name:	Catheter, cannula and tubing, vascular, cardiopulmonary bypass
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification:	Class II
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Predicate Device:	INFANT VENT CATHETER 12001 W/SIDE VENT
Predicate 510(k) Number:	K834039, cleared January 3, 1984
Predicate Device:	ADULT VENT CATHETER
Predicate 510(k) Number:	K834352, cleared January 27, 1984
Reference Device:	California Medical Laboratories Inc. Malleable Vent Catheter
Reference 510(k) Number:	K981601, cleared July 28, 1998

Device Description:

The Medtronic DLP Left Heart Vent Catheters are used in procedures requiring cardiopulmonary bypass and have been on the market since 1984. The subject devices are indicated for use in venting the left heart during cardiopulmonary bypass (CPB) surgery up to 6 hours. The target group for this device is adult and pediatric patients undergoing CPB surgery where the removal of blood and air from the left heart is required.

- The DLP Malleable PVC Left Heart Vent consists of a flexible plastic tube with a perforated distal segment. A malleable thin wire within the catheter tube permits precise shaping. Depth markings on the tube indicate insertion depth.
- The DLP PVC Left Heart Vent with a preformed or malleable introducer consists of a flexible plastic tube with a perforated distal segment. The perforated end terminates in a closed tip to aid in the insertion of the proximal end of the catheter through the mitral valve. Depth markings on the tube indicate insertion depth.
- The DLP Silicone Left Heart Vent consists of a flexible silicone tube with a perforated 8.9 cm (3.5 in) distal segment. A small tapered silicone tip is attached to the perforated distal end to aid in the insertion of the catheter through the mitral valve. A malleable stainless steel introducer is provided with the catheter. Depth markings on the tube indicate insertion depth.

These devices are sterile, nonpyrogenic, and intended for single use only. Per ISO 10993-1, DLP Left Heart Vent Catheters are considered external communicating devices with direct contact with circulating blood for limited duration < 24 hours.

Indications for Use:

This catheter is indicated for use in venting the left heart during cardiopulmonary bypass (CPB) surgery up to 6 hours.

Contraindications:

Use the device only as indicated.

Target Patient Populations:

The target group for this device is adult and pediatric patients undergoing CPB surgery where the removal of blood and air from the left heart is required.

Substantial Equivalence:

Substantial equivalence analysis includes a comparison to the predicate device. The DLP Left Heart Vent Catheters design, principles of operation, and fundamental scientific technology are substantially equivalent to the predicate devices, Infant Vent Catheter 12001 W/Side Vent (K834039) and Adult Vent Catheter (K834352).

Comparison to Predicate:

A comparison of the DLP Left Heart Vent Catheters to the predicate devices indicates the following similarities:

- Same indications for use
- Same operating principle
- Same connector
- Same catheter body materials of construction
- Same luer cap (vented models only)
- Same sterilization method and assurance level (SAL)
- Same packaging configuration
- Did not require clinical data to verify safety and efficacy.

The following device modification was made to the predicate device:

- Additional Sizes
- Catheter Body Design (addition of embedded malleable wire)
- Tip Configuration
- Length
- Diameter
- Tip Vent Holes
- Tip Vent Hole Diameter
- Shelf Life

Summary of Performance Data

Testing has demonstrated the DLP Left Heart Vent Catheters are substantially equivalent to the predicate device. The tests identified below were conducted to demonstrate substantial equivalence of the proposed device to the predicate device.

Performance Testing

- Cannula Body Outer Diameter
- Cannula Body Length
- Cannula Tip Hole Presence
- Depth Mark Locations
- Printing Visibility
- Printing Durability
- Luer Port Presence

- Vacuum Collapse
- Bend Angle Retention
- Crack, Split, Kink
- Malleable Body Fatigue
- Connector Detachment
- Tip Detachment
- Cannula Tip Visibility

Biocompatibility Testing

- Chemical Characterization and Toxicological Risk Assessment
- Cytotoxicity Testing
- Sensitization Testing
- Intracutaneous Irritation Testing
- In Vitro Skin Irritation Assay Testing
- Material Mediated Pyrogenicity Testing
- Acute Systemic Toxicity Testing
- Hemolysis (direct and extract) Testing
- Complement Activation Testing
- Partial Thromboplastin Time (PTT) Testing
- Platelet and Leukocyte Testing

Conclusion:

The data included in this submission demonstrates that the modified DLP Left Heart Vent Catheters are substantially equivalent to the legally marketed predicate devices, Infant Vent Catheter 12001 W/Side Vent (K834039) and Adult Vent Catheter (K834352).