February 19, 2026

Medtronic Inc.
Megan Smith
Senior Regulatory Affairs Specialist
8200 Coral Sea St NE
Mounds View, Minnesota 55112

Re: K253203
Trade/Device Name: Retrograde Coronary Sinus Perfusion Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: January 12, 2026
Received: January 12, 2026

Dear Megan Smith:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Meaghan Erlewein -S

For 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.	K253203

Please provide the device trade name(s).

Retrograde Coronary Sinus Perfusion Cannulae

Please provide your Indications for Use below.

These cannulae are indicated for CPB procedures requiring delivery of cardioplegia in a retrograde direction through the coronary sinus for up to 6 hours in duration.

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

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

510(k) Summary of Safety and Effectiveness

Date Prepared: September 26, 2025

Applicant:
Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person:
Megan Smith, PhD
Senior Regulatory Affairs Specialist
Email: smithm146@medtronic.com

Diane Howell (Alternate)
Regulatory Affairs Manager
Email: diane.d.howell@medtronic.com

Trade Name: Retrograde Coronary Sinus Perfusion Cannulae

Device Name: Catheter, cannula and tubing, vascular, cardiopulmonary bypass

Regulation Description: Cardiopulmonary bypass vascular catheter, cannula, or tubing

Classification: Class II

Regulation Number: 21 CFR 870.4210

Product Code: DWF

Predicate Device: VENOUS PERFUSION CANNULA W/CUFF CAT. NO. 94015 (K860149)
RETROGRADE CORONARY SINUS PERFUSION CANNULA WITH ELONGATED & TREADED CUFF & INTRODUCER STYLET (K953945)

Device Description:

The Retrograde Coronary Sinus Perfusion Cannulae models in scope of this 510(k) consist of a wire-wound silicone cannula body with a beveled tip (6-Fr models have a non-wire wound cannula body). Two side holes are present near the tip. The back of the cannula body terminates in a locking female luer. A pressure monitoring line is an integral part of the cannula body, beginning at the tip and terminating in a locking female luer fitting or 3-way stopcock with a locking female luer fitting. An inflatable balloon is located at the distal beveled tip. The inflation assembly is located at the back of the cannula body and contains a female slip luer and a one-

way valve assembly. Cannulae have a guidewire or solid stylet with a male luer handle or a Tru-Touch handle.

Indications for Use:

These cannulae are indicated for CPB procedures requiring delivery of cardioplegia in a retrograde direction through the coronary sinus for up to 6 hours in duration.

Target Patient Populations:

The target group for these devices is adult and pediatric patients eligible for CPB procedures.

Substantial Equivalence:

The design, principles of operation, and fundamental scientific technology of the Retrograde Coronary Sinus Perfusion (RCSP) Cannula models with added pediatric population were found to be substantially equivalent to the predicate devices cleared under K860149 and K953945.

Comparison to Predicate:

A comparison of the RCSP Cannula to the predicate device indicates the following similarities:

- Same intended use
- Equivalent labeling
- Equivalent technological characteristics
- Same operating principle
- Same design features
- Same sterilization requirements, methods, and parameters
- Same shelf-life
- Same packaging materials and configuration
- Similar materials of construction

The following device modification was made to the predicate device:

- Expanded patient populations (pediatric)

Summary of Performance Data

Pre-clinical bench testing was used to verify the suitability of cannula for pediatric populations. Bench testing was also used to confirm the performance of the 6 Fr Cannula body. Design outputs demonstrated conformance to the design input requirements defined in the testing protocol.

The following tests, including functional performance testing, blood trauma testing, and biocompatibility testing, were conducted on the RCSP devices.

Performance Testing

- Kink Testing
- Clamp Testing
- Leak Testing with Air
- Leak Testing with Water
- Luer tensile Testing
- Introducer Tensile Testing
- Introducer Twist Testing

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

Conclusion:

The data included in this submission are sufficient to demonstrate that the Retrograde Coronary Sinus Perfusion (RCSP) Cannulae with expanded pediatric patient target population are substantially equivalent to the predicate devices cleared under K860149 and K953945 and does not raise new questions of safety or effectiveness.