January 20, 2026

Medtronic, Inc.
Cassie Rominski
Principal Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K253998
Trade/Device Name: Clearview Intracoronary Shunts
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 12, 2025
Received: December 12, 2025

Dear Cassie Rominski:

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.

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,

SAMUEL G. RABEN -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention 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)*
K253998

Device Name
Clearview Intracoronary Shunts

Indications for Use *(Describe)*
The device is indicated for temporary use during the creation of anastomosis for medical conditions requiring beating heart coronary artery bypass procedures.

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.

510(k) Summary

Date Prepared: January 9, 2026

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

Contact Person:
Cassie Rominski
Principal Regulatory Affairs Specialist
Email: cassie.rominski@medtronic.com

Kimberly Peterson (Alternate)
Regulatory Affairs Director, Cardiac Surgery
Email: kimberly.m.peterson@medtronic.com

Trade Name: Clearview™ Intracoronary Shunts

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: Clearview™ Intracoronary Shunts (K120612)

Device Description:

The disposable intracoronary shunts consist of a flexible tube. Both ends of the tube feature a teardrop shaped tip made from radiopaque material with 14 mm between the ends. Tip diameters range from 1.00 mm to 3.00 mm. A tether with a tag made of radiopaque material is permanently attached to the shunts. These devices are sterile, nonpyrogenic, disposable and intended for single use only. They are sterilized using ethylene oxide and are categorized as external communicating devices, with limited contact (≤24 hours) circulating blood contact.

Indications for Use:

The device is indicated for temporary use during the creation of anastomosis for medical conditions requiring beating heart coronary artery bypass procedures.

Intended Purpose (Intended Use):

These devices are intended to shunt blood from the anastomotic site of a coronary artery while providing blood flow to the distal myocardium during beating heart coronary artery bypass procedures.

Target Patient Populations:

The patient target group for this device is adult patients undergoing beating heart coronary artery bypass where the shunting of blood at the anastomotic site is required.

Substantial Equivalence:

The design, principles of operation, materials of construction, performance and fundamental scientific technology of the Intracoronary Shunt models with modified indications for use, labeling updates and packaging were found to be substantially equivalent to the predicate device, Clearview Intracoronary Shunts (K120612).

Comparison to Predicate:

A comparison of the Intracoronary Shunts to the predicate device is based on the following technological characteristics:

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

The following device modifications were made to the predicate device:

- Modified indications and labeling updates
- Equivalent packaging materials and configuration

Conclusion:

The data included in this submission are sufficient to demonstrate that the Clearview Intracoronary Shunts with modified indications and labeling updates are substantially equivalent to the predicate devices, Clearview Intracoronary Shunts (K120612) and does not raise new questions.