April 23, 2026

Medtronic, Inc.
Nina Vollmer
Senior Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55122

Re: K260195
Trade/Device Name: Elongated One-Piece Arterial (EOPA) 3D™ Arterial 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 22, 2026
Received: January 22, 2026

Dear Nina Vollmer:

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 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,

Kathleen M. Grunder -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.	K260195

Please provide the device trade name(s).

Elongated One-Piece Arterial (EOPA) 3D™ Arterial Cannulae

Please provide your Indications for Use below.

These arterial cannulae are indicated for perfusion of the ascending or descending aorta for conditions requiring CPB procedures up to 6 hours in duration.

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: April 22, 2026

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

Contact Person: Nina Vollmer, PhD
Senior Regulatory Affairs Specialist
Email: nina.vollmer@medtronic.com

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

Trade Name: Elongated One-Piece Arterial (EOPA) 3D™ 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: EOPA 3D Arterial Cannula (K150422); Models 78220,78222,78320,78322

Device Description:

The EOPA 3D™ Arterial Cannulae consist of a flexible, thin-walled, wirewound body with a tapered distal tip. The tip features depth markings and an adjustable radiopaque suture ring to indicate insertion depth. The proximal end of the cannula terminates in a 0.95 cm (0.37 in) vented or non-vented connector. An obturator is provided to facilitate cannula insertion and priming. Multiple depth markings, catalog code, and French size are printed on the cannula body. Overall length of the cannula is approximately 31.8 cm (12.5 in). The device is sterile, nonpyrogenic, and single use only. It is sterilized using ethylene oxide.

Indications for Use:

These arterial cannulae are indicated for perfusion of the ascending or descending aorta for conditions requiring CPB procedures up to 6 hours in duration.

Substantial Equivalence:

The design, principles of operation, and fundamental scientific technology of the EOPA 3D™ Arterial Cannulae models were found to be substantially equivalent to the predicate device, EOPA 3D Arterial Cannula (K150422).

Comparison to Predicate:

A comparison of the EOPA 3D™ Arterial Cannulae to the predicate device indicates the following similarities:

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

The following modifications were made to the predicate device:

- Updated indications for use to include descending aorta, added an intended purpose and other minor labeling changes.

Conclusion:

The data included in this submission (K260195) are sufficient to demonstrate that the EOPA 3D™ Arterial Cannulae with modified labeling are substantially equivalent to the predicate device, EOPA 3D Arterial Cannula (K150422), and do not raise new questions of safety or effectiveness.