June 20, 2025

Medtronic, Inc
Stephen Beier
Senior Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K251258
Trade/Device Name: MC2™ Two-Stage Venous Cannula; MC2X™ Three-Stage Venous Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 23, 2025
Received: April 23, 2025

Dear Stephen Beier:

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,

Rachel E. Neubrander -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

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)*
K251258

Device Name
MC2™ Two-Stage Venous Cannula
MC2X™ Three-Stage Venous Cannula

Indications for Use *(Describe)*
This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety and Effectiveness

Date Prepared: June 20, 2025

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

Contact Person: Stephen Beier, RAC
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Diane Howell (Alternate)
Regulatory Affairs Manager
Email: diane.d.howell@medtronic.com

Trade Name: MC2™ Two-Stage Venous Cannula
MC2X™ Three-Stage Venous Cannula

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: MC2™ Two-Stage Venous Cannula, MC2X™ Three-Stage Venous Cannula (K140165)

Device Description:

The MC2™ Two-Stage Venous Cannula and MC2X™ Three-Stage Venous Cannula models feature wire wound polyvinyl chloride (PVC) bodies with side ports in the distal tip, a ported atrial basket drainage site located along the length of the cannula body, and a 3/8-inch (0.95 cm) to 1/2-inch (1.27 cm) connection site. The overall length of each cannula body is approximately 15¼ inch (38.7 cm). Insertion depth marks are provided to aid in positioning of the cannula. Each cannula is nonpyrogenic, is intended for single use, and has been sterilized using ethylene oxide.

Indications for Use:

This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

Substantial Equivalence:

The design, principles of operation, and fundamental scientific technology of the modified MC2™ Two-Stage Venous Cannula and MC2X™ Three-Stage Venous Cannula models were found to be substantially equivalent to the predicate device, MC2™ Two-Stage Venous Cannula and MC2X™ Three-Stage Venous Cannula, previously cleared in K140165.

Comparison to Predicate:

A comparison of the MC2™ Two-Stage Venous Cannula and MC2X™ Three-Stage Venous 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:

- Cannula body material formulation change

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device with the material formulation change. Testing was also conducted on aged samples to confirm that the changed cannula body material did not have an impact on cannula shelf life. Testing was conducted under both accelerated as well as real time conditions. 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 to support the material formulation change.

Performance Testing
Occluder Removal Testing, Vacuum Collapse Testing, Ink Adhesion Testing, Kink Under Bend Testing, Pressure Integrity Testing, Clamp Leak Rate and Clamp Site Drainage Testing, and Tensile Strength Testing (including Body-to-Connector Bond Strength and Strength of Bonds within Cannula Body)
Blood Trauma Testing
Plasma-free Hemoglobin Testing, White Blood Cell Reduction and Platelet Reduction Testing, and Hemolysis 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, Hemolysis Assay Testing – Direct Contact and Extract Method, Complement Activation Assay Testing, Partial Thromboplastin Time (PTT) Testing, and Platelet and Leukocyte Count Testing

Conclusion:

The data included in this submission are sufficient to demonstrate that the modified MC2™ Two-Stage Venous Cannula and MC2X™ Three-Stage Venous Cannula are substantially equivalent to the predicate device, MC2™ Two-Stage Venous Cannula and MC2X™ Three-Stage Venous Cannula (K140165) and does not raise new questions of safety or effectiveness.