March 27, 2025

Medtronic, Inc.
Samiksha Tiwari
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K250558
Trade/Device Name: SelectSite C304 Deflectable Catheter System (C304); C315 Delivery System (C315)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 24, 2025
Received: February 25, 2025

Dear Samiksha Tiwari:

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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2025.03.27 08:59:37 -04'00'

Sara Royce
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250558

Device Name
SelectSite C304 Deflectable Catheter System (C304);
C315 Delivery System (C315)

Indications for Use *(Describe)*
C315: This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads into the right chambers of the heart. The leads are implanted in patients who are indicated for a cardiac implantable electronic device (CIED) for treatment of heart rhythm disorders. Refer to the respective CIED instructions for use for details about the types of heart rhythm abnormalities or patient conditions treated by each type of CIED.

C304: This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads into the right chambers of the heart. The leads are implanted in patients who are indicated for a cardiac implantable electronic device (CIED) for treatment of heart rhythm disorders. Refer to the respective CIED instructions for use for details about the types of heart rhythm abnormalities or patient conditions treated by each type of CIED.

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

Submitter Information

Date Prepared:	February 25, 2025
Submitter:	Medtronic, Inc. Cardiac Rhythm Management 8200 Coral Sea Street NE Mounds View, MN 55112 ERN: 2182208
Contact Person:	Samiksha Tiwari Sr Regulatory Affairs Specialist Phone: 404-429-7275 email: Samiksha.tiwari@medtronic.com
Alternate Contact:	Dustin Hawbaker Sr Regulatory Affairs Manager Phone: 952-256-3711 email: dustin.hawbaker@medtronic.com

General Information

Trade Name:	SelectSite C304 Deflectable Catheter System C315 Delivery System
Common Name:	Catheter Delivery System
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Classification:	Class II
Classification Panel:	Cardiovascular
Predicate Device: *(SelectSite C304 Deflectable Catheter System)*	SelectSite C304 Deflectable Catheter System
Predicate Device: *(C315 Delivery System)*	C315 Delivery Catheter

Device Description

C315 Delivery System

The Medtronic C315 Delivery System contains one catheter and one dilator constructed of Polyether Block Amide and Polyethylene respectively. It is designed to aid in the introduction of various types of pacing or defibrillator leads and catheters. There are seven models in the Medtronic C315 Delivery Catheter product family, all of which have the same inner and outer diameter (5.4Fr and 7.0Fr respectively). The models differ in useable length, which varies from 20cm to 43cm. Proximally, the C315 is equipped with a hemostatic valve, and the distal tip is radiopaque to facilitate imaging under fluoroscopy. The C315 is designed to be slittable, thereby allowing its removal after device placement. A variety of curves are available to accommodate various anatomies and different lead locations.

SelectSite C304 Deflectable Catheter System

The SelectSite C304 Deflectable Catheter System contains a single deflectable catheter, deflectable catheter dilator, universal slitter, valve, guidewire, needle, and syringe. The SelectSite C304 Deflectable Catheter System is designed to access the coronary sinus and the chambers of the heart. The percutaneous needle and syringe are used to access to venous insertion site, the guidewire to access the vein, the introducer valve to reduce blood loss during the implant procedure, the deflectable catheter to introduce a transvenous device, the deflectable catheter dilator to facilitate deflectable catheter passage and the guide catheter slitter to remove the deflectable catheter. The SelectSite C304 Deflectable Catheter System is available in three models which are the C304-S59, C304-L69, and C304-XL74. All components except the deflectable catheter and dilator are identical in each model.

Indications for Use

C315 Delivery System

This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads into the right chambers of the heart. The leads are implanted in patients who are indicated for a cardiac implantable electronic device (CIED) for treatment of heart rhythm disorders. Refer to the respective CIED instructions for use for details about the types of heart rhythm abnormalities or patient conditions treated by each type of CIED.

SelectSite C304 Deflectable Catheter System

This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads into the right chambers of the heart. The leads are implanted in patients who are indicated for a cardiac implantable electronic device (CIED) for treatment of heart rhythm disorders. Refer to the respective CIED instructions for use for details about the types of heart rhythm abnormalities or patient conditions treated by each type of CIED.

Technological Characteristics

The technology of the subject devices is identical to the respective predicates. There are no changes to the design, physical characteristics, materials, packaging, or sterilization presented in this submission. The subject devices have identical indications for use to the respective predicate devices. The intended use of the catheters, to introduce transvenous devices to the heart, remains the same.

When compared to the predicate devices, the subject C315 Delivery System and subject SelectSite C304 Deflectable Catheter System presented in this submission have the same:

- Intended use
- Operating principle
- Design features
- Device functionality
- Biological safety
- Packaging materials
- Shelf life

The subject C315 Delivery System and SelectSite C304 Deflectable Catheter System devices differ from the respective predicates in that the subject devices have updated instructions for use (IFU) to indicate warning for potential small-bore misconnection.

Substantial Equivalence and Conclusion

The labeling modification is supported by verification activities and makes the products compliant with clause 7f of ISO 80369-7.

The subject devices are substantially equivalent to the specified predicate devices based on comparisons of the indications for use, intended use, device functionality, and technological characteristics.