November 8, 2022

Medtronic
Sarah Meyer
Senior Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K223178
Trade/Device Name: SelectSite C304 Deflectable Catheter System, C315 Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 10, 2022
Received: October 11, 2022

Dear Sarah Meyer:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Hetal B. Patel -S

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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)*
K223178

Device Name
C315 Delivery System

Indications for Use *(Describe)*
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.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

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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)*
K223178

Device Name
SelectSite C304 Deflectable Catheter System

Indications for Use *(Describe)*
This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads 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.

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510(k) Summary

Date Prepared: October 10, 2022

Submitter: Medtronic, Inc.
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8200 Coral Sea Street N.E.
Mounds View, MN 55112
Establishment Registration Number: 2182208

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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

SelectSite C304 Deflectable Catheter System
The SelectSite C304 Deflectable Catheter System contains 1 deflectable catheter, 1 deflectable catheter dilator, 1 universal slitter, 1 valve, 1 guidewire, 1 needle and 1 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 the 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.

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.

Indications for Use

SelectSite C304 Deflectable Catheter System
This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads 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.

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.

Technological Characteristics
The technology of the subject devices is identical to the respective predicates. Compared to the predicate devices, the subject devices have updated instructions for use (IFU) to indicate a larger compatible lead size. There are no changes to the design, physical characteristics, materials, packaging, or sterilization presented in this submission. The subject devices have similar 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 SelectSite C304 Deflectable Catheter System and subject C315 Delivery System presented in this submission have the same:

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

The subject SelectSite C304 Deflectable Catheter System and C315 Delivery System devices differ from the respective predicates in that the subject devices have updated instructions for use (IFU) to indicate a larger compatible lead size.

Substantial Equivalence and Summary of Studies

The labeling modifications regarding compatible lead size to the subject device are supported through design verification activities. All design verification activities were completed successfully. The subject devices are substantially equivalent to the specified predicate devices based on comparisons of the intended use, device functionality, and technological characteristics.

Conclusion

The results of the verification testing met the specified acceptance criteria and did not raise new or different questions of safety or effectiveness. Therefore, the labeling modifications for the C315 Delivery System and SelectSite C304 Deflectable Catheter System described in this submission result in a device that is substantially equivalent to the respective predicates.