March 15, 2019

Medtronic Inc.
Linda O'Connor
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K183493
Trade/Device Name: SELECTSITE C304-HIS Deflectable Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 14, 2018
Received: December 17, 2018

Dear Linda O'Connor:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Digitally signed by Hetal B. Patel -S
Date: 2019.03.15 07:16:01 -04'00'

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183493

Device Name
SELECTSITE C304-HIS Deflectable Catheter System

Indications for Use *(Describe)*
The device is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

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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K183493 – 510(k) Summary

510(k) Summary per 21 CRF 807.92

Date Prepared:

16 November 2018

Applicant:
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Common Name:

SelectSite™ C304-HIS Delivery Catheter

Device Classification:

II

Regulation Number:

21 CFR 870.1250

Classification Name:

Percutaneous Catheter

Product Code:

DQY

Device Description:
The C304-HIS device is a radio opaque, braid-reinforced catheter with a deflectable distal tip. The catheter shaft is constructed from Polyether Block Amid (PEBA), with a medical stainless-steel braid and an inner Polytetrafluoroethylene (PTFE) liner. The shaft construction is manufactured by an external vendor Teleflex. The shape of the distal catheter deflectable segment is controlled by a pull wire connected to the handle which can be adjusted to accommodate individual anatomies and to allow access to the target sites. The pull wire is anchored to a distal gold marker band.

The device features a guide wire to access the vein, a valve to reduce blood loss during the implant procedure, a deflectable catheter to introduce a transvenous device, a catheter dilator to facilitate deflectable catheter passage, and a guide catheter slitter to remove the deflectable catheter. The deflectable catheter is designed for placement of transvenous devices in or near the bundle of His. It features a deflecting distal section, controlled by the deflectable catheter handle, and an out-of-plane curve on the distal tip. The body of the deflectable catheter is radiopaque for visibility on fluoroscopy.

Indications For Use:
The deflectable catheter system is indicated to provide a pathway though which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Substantially Equivalent Device:
The C304-HIS device uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate device:

- SelectSite™ C304-S5901 and C304-L6901 Deflectable Catheter Systems (K033989, cleared January 22, 2004 and K061416, cleared October 26, 2006)

The SelectSite™ C304HIS Catheter System is similar in shape to the following reference device:

C315 Delivery Catheter (K101885, Cleared September 9, 2010)

Summary of Technological Differences to the Predicate Device:
The C304-HIS device will have a fixed curve shape design at the distal end, which is not present in the existing C304 catheter models.

The C304-HIS device was designed to optimize placement of transvenous devices in or near the bundle of His.

Summary of Non-Clinical Data:
Device integrity testing was performed to support the equivalency of the C304-HIS device to the predicate devices. Testing included mechanical, functional, and biocompatibility testing. The C304-HIS device met all specified design and performance requirements.

Biocompatibility Information:
The biocompatibility evaluation completed for the C304-HIS device verifies that the C304-HIS device is biocompatible. The testing which supports the biocompatibility of the C304-HIS device is consistent with International Standard ISO 10993-1: “Biological Evaluation

of Medical devices- Part 1: Evaluation and Testing." When classified according to this standard, the catheter and dilator included in the C304-HIS device are external communicating devices with limited exposure (<24 hours) to circulating blood.

Summary of Clinical Data:

Clinical data was not generated. This section is not applicable.

Sterilization Validation:

The C304-HIS device will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion:

Through the data and information presented, Medtronic considers the C304-HIS device to be substantially equivalent to legally marketed predicate devices.