August 3, 2020

Medtronic, Inc.
Nicola Reidy
Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K192712
Trade/Device Name: Attain Select™ II + SureValve™ Delivery Catheter System, Attain Command™ + SureValve™ Left Heart Delivery System, Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery, C315 Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 2, 2020
Received: July 6, 2020

Dear Nicola Reidy:

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 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

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)*
K192712

Device Name
Attain Command™ + SureValve™ Left Heart Delivery System;
Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery

Indications for Use *(Describe)*
The left-heart delivery system is intended for introducing transvenous devices and 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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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:

Department of Health and Human Services
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192712

Device Name
Attain Select™ II + SureValve™ Delivery Catheter System

Indications for Use *(Describe)*
The Attain Select™ II + SureValve™ delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left-heart venous anatomy. The delivery catheter system is indicated for use with outer guide catheters.

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)

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192712

Device Name
C315 Delivery Catheter

Indications for Use *(Describe)*
The C315 is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

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 per 21 CRF 807.92

Date Prepared:
26 September 2019

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Common Name:

- C315 Delivery Catheter
- Attain Select™ II + SureValve™ delivery catheter system
- Attain Command™ + SureValve™ Product families (Left Heart Delivery System & Guide Catheters for Left Heart Delivery)

Device Classification:

II

Regulation Number:

21 CFR 870.1250

Classification Name:

Percutaneous Catheter

Product Code:

DQY

Device Description:
The Medtronic C315 Delivery Catheter 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.

The Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus. The Attain Command™ + SureValve™ Left-Heart Delivery System kits each contain two outer guide catheters with an integrated hemostasis valve (SureValve™), up to two valve tools, one dilator, one guide wire, and one slitter. The Attain Command™ + SureValve™ Left-Heart Delivery System is available in two models:

- Attain Command™ + SureValve™ 6250VC Left Heart Delivery System
- Attain Command™ + SureValve™ 6250VS Left Heart Delivery System

With the exception of the two guide catheters, all system components packaged in each kit are identical. Each guide catheter model is different with respect to the guide catheter shape and length.

The Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery individual packs each contain one guide catheter with an integrated hemostasis valve (SureValve™), up to two valve tools, and one dilator. The Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are available in 12 models:

- Attain Command™ + SureValve™ 6250V-45S Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-50S Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-57S Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-AM Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-EH Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-EHXL Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MB2 Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MB2X Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MP Guide Catheter for Left Heart Delivery

- Attain Command™ + SureValve™ 6250V-MPR Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MPX Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-3D Guide Catheter for Left Heart Delivery

Each model is different with respect to the guide catheter shape and length and dilator length.

The Attain Select™ II + SureValve™ delivery catheter system is designed to facilitate left-heart lead delivery to a desired cardiac vein. The Attain Select™ II + SureValve™ delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left-heart venous anatomy. The delivery catheter system is indicated for use with outer guide catheters. Together, the catheters function as a telescoping system that can provide additional sub selecting capabilities.

The delivery catheter system consists of a delivery catheter with an integrated hemostasis valve (SureValve™), an inner catheter, and up to two valve tools. The Attain Select™ II + SureValve™ delivery catheter system is available in 8 models:

- Attain Select™ II + SureValve™ 6248V-90 Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90S Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90L Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-130 Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-130L Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90P Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90SP Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-130P Delivery Catheter System

The Attain Select™ II + SureValve™ inner catheter is identical for all configurations. Each model is different with respect to delivery catheter shape and length.

Indications For Use:
The indications for use for each of the applicable devices is listed below;

- C315 Delivery Catheter

The device is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

- Attain Command™ + SureValve™ Left Heart Delivery System
- Attain Command™ & SureValve™ Guide Catheters for Left Heart Delivery:

The left-heart delivery system is intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus.

- Attain Select™ II + SureValve™ Delivery Catheter System:

The Attain Select™ II + SureValve™ delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left-heart venous anatomy. The delivery catheter system is indicated for use with outer guide catheters.

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

- C315 Delivery Catheter (K101885, cleared on September 9, 2010)
- Attain Select™ II + SureValve™ delivery catheter system (K123153, cleared on April 9, 2013)
- Attain Command™ + SureValve™ Product families (Left Heart Delivery System and Guide Catheters for Left Heart Delivery) (K123153, cleared on April 9, 2013)

Summary of Technological Differences to the Predicate Device:
The difference to the predicate device is the change in the tip material.

	Current Tip Material	**Proposed Tip Material**
Materials	Tungsten Carbide Pebax material	Tungsten Carbide Pebax material with addition of hydrolysis inhibitor stabilizer and a hindered amine light stabilizer.

Summary of Non-Clinical Data:
Device integrity testing was performed to support the equivalency of the tip material change of the applicable devices device to the predicate devices. Testing included mechanical, functional, sterilization and biocompatibility testing. The devices listed below met all specified design and performance requirements.

- C315 Delivery Catheter (K101885, cleared on September 9, 2010)
- Attain Select™ II + SureValve™ delivery catheter system (K123153, cleared on April 9, 2013)
- Attain Command™ + SureValve™ Product families (Left Heart Delivery System and Guide Catheters for Left Heart Delivery) (K123153, cleared on April 9, 2013)

Biocompatibility Information:
The biocompatibility evaluation completed for the devices listed below verifies that the applicable devices are biocompatible.

- C315 Delivery Catheter
- Attain Select™ II + SureValve™ delivery catheter system

- Attain Command™ + SureValve™ Product families (Left Heart Delivery System and Guide Catheters for Left Heart Delivery)

The testing which supports the biocompatibility 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 applicable devices 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 applicable devices will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion:
Through the data and information presented, Medtronic Ireland considers the

- C315 Delivery Catheter
- Attain Select™ II + SureValve™ delivery catheter system
- Attain Command™ + SureValve™ Product families (Left Heart Delivery System and Guide Catheters for Left Heart Delivery)

device with the tip material change to be substantially equivalent to legally marketed predicate devices:

- C315 Delivery Catheter
- Attain Select™ II + SureValve™ delivery catheter system
- Attain Command™ + SureValve™ Product families (Left Heart Delivery System and Guide Catheters for Left Heart Delivery)