Creganna Medical
Olivia Odhiambo
Senior Regulatory Affairs Specialist
Parkmore West
Galway, Ireland

Re: K171819
Trade/Device Name: Attain Assist CS Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 6, 2017
Received: December 6, 2017

Dear Olivia Odhiambo:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171819

Device Name

Attain Assist™ CS Access Catheter

Indications for Use *(Describe)*

The Attain Assist™ CS Access Catheter is a left-heart CS catheter intended to enable access to 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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510(k) Summary

General Information

Date:	15 June 2017
Classification:	Class II, 21 CFR 870.1250, Percutaneous Catheter
Product Code:	DQY
Trade Name:	Attain Assist™ CS Access Catheter
Common Name:	Percutaneous Catheter
Model Number(s):	146168-01
Submitter:	Creganna Medical, Parkmore West, Galway, Ireland
Regulatory Contact:	Orla Connaughton Regulatory Affairs Director Creganna Medical Parkmore West Galway, Ireland Tel: + 91 783469 Email: CREG-GALRegulatory@te.com

Intended Use

The Attain Assist™ CS Access Catheter is a left-heart CS catheter intended to enable access to the left heart via the coronary sinus.

Predicate Device

- Attain Command™ + SureValve™ Guide Catheter, K123153

Device Description

The Medtronic Attain Assist™ CS Access Catheter is a sterile, single-use intravascular catheter used to facilitate access to the left heart via the coronary sinus.

The device consists of a braid reinforced catheter shaft with a curve at the distal end and a hub luer connection with a strain relief and a detachable cap at the proximal end of the device. The detachable cap

prevents leakage from the catheter when a guide wire is not being used. At the distal end of the catheter shaft, six (6) radiopaque marker bands are embedded into the shaft which provide a visual aid under fluoroscopy during device positioning in the left heart. A stainless steel tip is attached to the distal edge of the braided catheter shaft to provide an atraumatic lead for the catheter during delivery.

The Attain Assist™ CS Access Catheter is compatible with guide catheters with inner diameter of 6.5Fr or greater.

The device is supplied as a single use sterile device.

Materials

The Attain Assist™ CS Access Catheter is comprised of materials that are commonly used in medical device applications, including implantable medical devices. The biological safety tests performed in accordance with ISO 10993-1 (Biological evaluation of medical devices -- Part 1: Evaluation and testing) for external communicating devices, circulating blood, limited duration demonstrate that the device is biocompatible for its intended use.

The tests performed to demonstrate the biocompatibility of the device were:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity/Irritation
- Acute Systemic Toxicity
- Hemocompatibility
- Thromboresistance
- Material Mediated Pyrogenicity

Comparison of Technological Characteristics of Attain Assist™ CS Access Catheter compared to the Predicate Device

The Attain Assist™ CS Access Catheter and the equivalent commercialized predicate device Attain Command™ + SureValve™ Guide Catheter were evaluated for substantial equivalence. No significant difference in clinical, technical and biological parameters was identified between the Attain Assist™ CS Access Catheter and the predicate device. Both devices have the same clinical principal of operation, i.e. advancement through the same anatomical locations to obtain access to the left heart via the coronary

sinus, in the same patient population with the same user group. Both devices are used in interventional coronary procedures. The technological specifications and characteristics are extremely similar, the slight differences relating primarily to the fact that the predicate device is a guide catheter and the proposed device is intended to be inserted within the guide catheter. Both devices have similar designs and the materials that are used meet the same biological standards. Based on this and the design and engineering data provided, the Attain Assist™ CS Access Catheter has been shown to be substantially equivalent to the commercialized Attain Command™ + SureValve™ Guide Catheter.

Non Clinical Information

The determination of substantial equivalence is also based on an assessment of non-clinical engineering tests, as listed in **Table 1-1** and **Table 1-2.**

Table 1-1: List of Design Verification Tests

Design Verification Tests	
Catheter Shaft And Tip Outer Diameter	Catheter Proximal Hub
Catheter Working Length	Package Sterility
Catheter Curvature	Seal Strength Of Sterile Package
Catheter Tensile Strength (Shaft, Hub To Shaft, Tip To Shaft)	Packaging Integrity (Including Seal Width)
Catheter Pressure Integrity	Labelling/IFU Integrity And Legibility
Catheter Guidewire Interface/Compatibility	Package Contents / Configuration
Kink Resistance	Patient Chart Stickers
Corrosion Resistance	Catheter Trackability
Catheter Shapeability	Ability To Withstand Environmental Conditions
Cap fitting (attachment to catheter hub leur)	

Table 1-2: List of Design Validation Tests (Bench)

Design Validation Tests	
Catheter Distal Marker Bands Radiopacity	Cap fitting (attachment to catheter hub leur)
Catheter Guidewire interface/compatibility	Compatibility of Attain Assist™ with the Attain Command™ device
Catheter Radio-detectability	Catheter Proximal Hub (ergonomic, Grip and handling)
Catheter Torque response	Removal of Product from Packaging
Catheter Trackability	IFU requirements - (easy to understand, language)
Catheter Shapeability	Labelling requirements – Pouch and carton Label (easy to understand, language, provide traceability, product identification, expiry date)
Hub Luer fitting (compatibility with syringe)	

The test results demonstrate that the Attain Assist™ CS Access Catheter meets the requirements in the applicable standards and specifications and is substantially equivalent to legally marketed predicate device.

Clinical Information

Clinical studies were not deemed necessary for the Attain Assist™ CS Access Catheter since bench testing was sufficient to demonstrate substantial equivalence by way of comparison to a legally marketed predicate device.

Summary of Substantial Equivalence

Creganna Medical believes the Attain Assist™ CS Access Catheter is substantially equivalent to the predicate device based on the nonclinical literature review as discussed above. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to an existing legally marketed predicate product (Attain Command™ + SureValve™ Guide Catheter).