November 21, 2018

Medtronic Vascular, Inc.
Janelle Wong Keller
Regulatory Affairs Specialist
3850 Brickway Boulevard
Santa Rosa, California 95403

Re: K182957
Trade/Device Name: Heli-FX EndoAnchor System
Regulation Number: 21 CFR 870.3460
Regulation Name: Endovascular Suturing System
Regulatory Class: Class II
Product Code: OTD
Dated: October 22, 2018
Received: October 24, 2018

Dear Janelle Wong Keller:

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,

Brian D. Pullin -S

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)*
K182957

Device Name
Heli-FX EndoAnchor System

Indications for Use *(Describe)*
The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX EndoAnchor system is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e., repair) procedure.

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

510(k) Number: K182957

General Information

Manufacturer

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432
Tel: (763) 514-4000

Contact Person

Janelle Wong Keller
Regulatory Affairs Specialist

Alternate Contact Person

Burt Goodson
Senior Principal Regulatory Affairs Specialist

Date Prepared

15 November 2018

Device Description

The Heli-FX™ EndoAnchor™ Systems are each comprised of the respective Heli-FX Applier with EndoAnchor Cassette, containing ten EndoAnchor implants; the respective Heli-FX Guides; and the Ancillary EndoAnchor Cassette, containing five EndoAnchor implants.

Generic/Common Name and Classification

Endovascular Suturing System (product code OTD) per 21 CFR 870.3460. Heli-FX™ EndoAnchor™ Systems (comprising the Heli-FX EndoAnchor system and Heli-FX thoracic EndoAnchor System) are Class II devices.

Trade Name

Heli-FX EndoAnchor System

- Heli-FX Applier with EndoAnchor Cassette containing ten (10) EndoAnchor implants
- Heli-FX Guide
- Ancillary EndoAnchor Cassette containing five (5) EndoAnchor implants

Predicate Devices

- Heli-FX EndoAnchor System per K171427

Intended Use

The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e., repair) procedure.

Product Description

The Heli-FX EndoAnchor System comprises the EndoAnchor implant, an intravascularly-applied suture, supplied with the Heli-FX Applier in a Cassette containing ten (10) EndoAnchor implants, or separately in an Ancillary Cassette containing five (5) EndoAnchor implants; the Heli-FX Applier, a catheter-based device for placement of the EndoAnchor; and the Heli-FX Guide, a deflectable sheath to position the Applier.

The EndoAnchor is an endovascularly-placed suture designed to attach aortic endografts to the native vessel wall. The EndoAnchor is manufactured from medical-grade nickel-cobalt wire and is wound in a helical shape. The leading end is sharpened to a conical point to act as an integral needle facilitating atraumatic deployment through the graft material and vessel wall. The proximal end of the EndoAnchor includes a diagonal crossbar, which functions as a suture anchor designed to prevent over penetration of the EndoAnchor. Ten (10) EndoAnchor implants are pre-packaged into a cassette, which is supplied with the Heli-FX Applier. The cassette is designed to facilitate easy and accurate loading of the EndoAnchor into the Applier catheter. EndoAnchor implants are also supplied separately in an Ancillary Cassette containing five (5) additional EndoAnchor implants.

The Heli-FX Applier is designed to implant the EndoAnchor. The Applier implants one EndoAnchor at a time, and can be used to implant multiple EndoAnchor implants in a single patient. The Applier is designed for use with the Heli-FX Guide. The Applier is a 12Fr (OD) catheter with an integrated control handle. Two Applier lengths are available for anchoring in different regions of the aorta.

The Heli-FX Guide is a sterile, single use, disposable device designed to direct the Heli-FX Applier to the desired location for EndoAnchor implantation. The device is compatible with a 0.035” Guide wire. The Heli-FX Guide consists of a 12 Fr-compatible (inner diameter) Guide sheath with integrated control handle, and a matching 12 Fr OD obturator. Deflection of the distal tip of the catheter is accomplished by rotating the Control Knob located on the control handle. The Guide is available in both 62cm (16Fr OD) and 90cm (18Fr OD) working lengths. Multiple deflectable tip lengths are available to accommodate a range of aortic diameters. The Obturator is

used during vessel access and is designed to follow the Guide wire and provide access through tortuous vasculature.

Special Controls

Special controls have been established for endovascular suturing systems per 21 CFR 870.3460(b). These special controls include specific requirements related to biocompatibility, sterility and shelf-life, performance testing, MR compatibility, electromagnetic compatibility and electrical safety, labeling, and the prescription-only status of the devices.

Substantial Equivalence

The Heli-FX EndoAnchor System and its intended use are identical to that cleared under K171427. The only difference that constitutes this Special 510(k) is the revision of the Heli-FX EndoAnchor System Instructions for Use to state that the Heli-FX EndoAnchor System is compatible with the Valiant Navion Stent Graft System. Adequate rationale was provided to support the compatibility of these systems based on the previously provided testing with the endografts that are currently listed as compatible with the Heli-FX EndoAnchor System in its IFU. Thus, no new testing with the Valiant Navion Stent Graft System was needed.

Summary

The data and information presented in this application, support a determination of substantial equivalence of the predicate device: Heli-FX EndoAnchor System.