

510(k) SUMMARY PER 21 CFR 807.92

AUG 8 2012

510(k) Number: K 121168**GENERAL INFORMATION:****Manufacturer:**

Aptus Endosystems, Inc.
777 North Pastoria Avenue
Sunnyvale, CA 94085
Tel: (408) 530-9050
Fax: (408) 530-9051

Contact Person:

Burt Goodson
Director, Scientific and Regulatory Affairs

Date Prepared:

April 16, 2012

DEVICE DESCRIPTION:

The Aptus 18Fr HeliFX Aortic Securement System comprises the EndoAnchor with EndoAnchor Cassette, the 18Fr HeliFX Applier, and the 18Fr HeliFX Guide.

Generic/Common Name and Classification:

Endovascular suturing system (OTD) per 21 CFR 870.3460

Trade Name:

Aptus 18Fr HeliFX Aortic Securement System

- Aptus EndoAnchor with EndoAnchor Cassette
- Aptus 18Fr HeliFX Applier
- Aptus 18Fr HeliFX Guide

PREDICATE DEVICES:

Aptus HeliFX Aortic Securement System (formerly Aptus EndoStapling System) per K102333

INTENDED USE:

The Aptus 18Fr HeliFX Aortic Securement System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The 18Fr HeliFX 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.

PRODUCT DESCRIPTION:

The Aptus 18Fr HeliFX Aortic Securement System comprises the EndoAnchor implant (an intravascularly-applied suture, supplied in a Cassette containing 10 EndoAnchors), the HeliFX Applier (a catheter-based device for placement of the EndoAnchor), and the HeliFX Guide (a deflectable sheath to position the Applier).

The Aptus 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) EndoAnchors are pre-packaged into a cassette, which is supplied sterile to the user. The cassette is designed to facilitate easy and accurate loading of the EndoAnchor into the Applier catheter.

The Aptus 18Fr HeliFX Applier is designed to implant the Aptus EndoAnchor. The Applier implants one EndoAnchor at a time, and can be used to implant multiple EndoAnchors in a single patient. The 18Fr Applier is designed for use with the 18F HeliFX Guide. The Applier is a 12Fr (OD) catheter with an integrated control handle.

The Aptus 18Fr HeliFX Guide is a sterile, single use, disposable device designed to direct the 18Fr HeliFX Applier to the desired location for EndoAnchor implantation. The device is compatible with a 0.035" guide wire. The 18Fr HeliFX 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. 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 substrating 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 various components of the 18Fr HeliFX System covered in this submission are substantially equivalent in materials, method of operation, and intended use as the prior HeliFX System cleared via K102333. Where specific dimensional and performance differences exist, bench testing has shown that these differences do not present new risks.

DATA RELIED UPON FOR SUBSTANTIAL EQUIVALENCE:

Data relied upon to demonstrate substantial equivalence of the Aptus 18Fr HeliFX System to the predicate, and to demonstrate conformance to special controls, includes the following:

- Performance and simulated use testing
- Mechanical integrity and characterization testing
- Endograft compatibility testing
- Sterilization, biocompatibility, and shelf-life evaluations

SUMMARY:

The Aptus 18Fr HeliFX System covered in this submission has been shown to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Aptus Endosystems
c/o Mr. Burt Goodson
Director, Scientific & Regulatory Affairs
777 North Pastoria Avenue
Sunnyvale, CA 94085

Re: K121168

Trade/Device Name: 18Fr HeliFX Aortic Securement System
Regulation Number: 21 CFR 870.3460
Regulation Name: Endovascular Suturing System
Regulatory Class: Class II (two)
Product Code: OTD

Dated: July 3, 2012

Received: July 5, 2012

Dear Mr. Goodson:

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.

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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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



B Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Aptus Endosystems, Inc.
777 N Pastoria Ave
Sunnyvale, CA 94085

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

K121168

Device Name:

Aptus 18Fr HeliFX Aortic Securement System

Indications for Use:

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Prescription Use

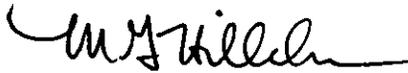
X

or

Over-the-counter Use

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division sign-off
Division of Cardiovascular Devices

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