DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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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: K102333
Aptus Endostapling System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 870.3460
Regulation Name: Endovascular Suturing System
Regulatory Classification: Class II (two)
Product Code: OTD
Dated: December 10, 2010
Received: December 14, 2010

Dear Mr. Goodson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the Aptus Endostapling System as a prescription device under 21 CFR Part 801.109 that is indicated for providing fixation and sealing between endovascular aortic grafts in the native artery. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Aptus Endostapling System, and substantially equivalent devices of this generic type, into class II under the generic name, Endovascular Suturing System.

FDA identifies this generic type of device as: Endovascular Suturing System.

Identification: An endovascular suturing system is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery. The system is comprised of the implant device and an endovascular delivery device used to implant the endovascular suture.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on November 12, 2010 automatically classifying the Aptus Endostapling System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On December 14, 2010, FDA filed your petition requesting classification of the Aptus Endostapling System into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Aptus Endostapling System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the Aptus Endostapling System indicated for providing fixation and sealing between endovascular aortic grafts in the native artery can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

Table - Potential Risks and Mitigations

Identified Risks and Proposed Mitigation Measures	
Identified Risk	**Recommended Mitigation Measures**
Adverse tissue reaction	Biocompatibility Labeling
Infection	Sterility and Shelf Life Testing
Incompatibility with endograft	Bench testing
Migration or fracture of the endovascular suture	Bench testing Animal testing Clinical evaluation
Imaging Incompatibility	Bench testing Labeling
Electromagnetic incompatibility	Electromagnetic Compatibility Labeling
Electrical safety issues	Electrical Safety Testing Labeling
Corrosion	Bench testing
Improper deployment or inability to deploy	Bench testing Animal testing Clinical Evaluation Software validation
Failure to prevent endograft migration or Type I endoleak	Bench testing Clinical evaluation Cadaver testing

In addition to the general controls of the FD&C Act, the Endovascular Suturing System is subject to the following special controls:

(1) The device should be demonstrated to be biocompatible; (2) Sterility and shelf life testing should demonstrate the sterility of patient-contacting components and the shelf-life of these components; (3) Non-clinical and clinical performance testing should demonstrate substantial equivalence in safety and effectiveness,, including durability, compatibility, migration resistance, corrosion resistance, and delivery and deployment; (4) Non-clinical testing should evaluate the compatibility of the device in an MR environment; (5) Appropriate analysis and non-clinical testing should validate electromagnetic compatibility (EMC) and electrical safety; (6) The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109; and (7) Labeling must bear all information required for the safe and effective use of the device as outlined in 801.109(c), including a detailed summary of the non-clinical and clinical evaluations pertinent to use of the device.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Endovascular Suturing System they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Robert Gill at 301-796-6373.

Sincerely yours,

Jonette Foy, Ph.D.
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health