



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2012-N-0091]

Medical Devices; Cardiovascular Devices; Classification of the Endovascular Suturing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the endovascular suturing system into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was effective on November 21, 2011.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), 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 predicate 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 regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will 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 announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on November 12, 2010, classifying the EndoStapling System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into

interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On December 10, 2010, Aptus Endosystems, Inc. submitted a petition requesting classification of the EndoStapling System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special 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 determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name endovascular suturing system, and it is identified as 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.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

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

FDA believes that the following special controls address the risks to health and provide reasonable assurance of the safety and effectiveness of the device: (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 magnetic resonance (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 (§ 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; in addition to general controls, address the risks to health and provide reasonable assurance of the safety and effectiveness of the

device. Therefore, on November 21, 2011, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 870.3460.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an endovascular suturing system will need to comply with the special controls named in the regulation.

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. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the endovascular suturing system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe *** a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where

the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. (See 21 U.S.C. 360(k); See Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996); Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)). The special controls established by this final rule create “requirements” to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360(k), even though product sponsors may have flexibility in how they meet those requirements (See Papike v. Tambrands, Inc., 107 F.3d 737, 740-42 (9th Cir. 1997)).

V. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 32501-3520). The collections of information in part 807 subpart E, regarding premarket notification submissions, have been approved under OMB control no. 0910-0120; the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control no. 0910-0485.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition: Request for Evaluation of Automatic Class III Designation under § 513(f)(2) of the Food, Drug, and Cosmetic Act from Aptus Endosystems, Inc., December 10, 2010.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 870.3460 is added to subpart D to read as follows:

§ 870.3460 Endovascular Suturing System.

(a) 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.

(b) Classification. Class II (special controls). The special controls for this device are:

(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 magnetic resonance (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 of this chapter; and

(7) Labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including a detailed summary of the non-clinical and clinical evaluations pertinent to use of the device.

Dated: February 9, 2012.

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