



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

Ethicon Endo-Surgery, Inc.
c/o Mr. Thomas Bosticco
Director, QS/RA
4545 Creek Road
M/L 131
Cincinnati, Ohio 45242

APR 30 2012

Re: K110431
Percutaneous Surgical Set with 5mm or 10mm Attachments
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 878.4790
Regulation Name: Manual Percutaneous Surgical Set Assembled in the Abdomen
Regulatory Classification: Class II
Product Code: OXT
Dated: September 20, 2011
Received: September 21, 2011

Dear Mr. Bosticco:

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 Percutaneous Surgical Set with 5mm or 10mm Attachments is a prescription device under 21 CFR Part 801.109 that is indicated for the means to penetrate soft tissue to access certain areas of the human abdomen and used to grasp, hold and manipulate tissue. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Percutaneous Surgical Set with 5mm or 10mm Attachments, and substantially equivalent devices of this generic type, into class II under the generic name, Manual Percutaneous Surgical Set Assembled in the Abdomen.

FDA identifies this generic type of device as:

Manual Percutaneous Surgical Set Assembled in the Abdomen. A device consisting of an percutaneous surgical set and accessories used as a means to penetrate soft tissue to access certain areas of the abdomen. The devices' effectors or attachments are provided separately from the percutaneous shaft and are introduced to the site via a traditional conduit such as a trocar. The attachment or effectors are connected to the shaft once the tip of the shaft is inside the abdomen. Once inside the abdomen, the surgical set is used to grasp, hold, and

manipulate soft tissues. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

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 August 26, 2011 automatically classifying the Percutaneous Surgical Set with 5mm or 10mm Attachments 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 September 20, 2011, FDA filed your petition requesting classification of the Percutaneous Surgical Set with 5mm or 10mm Attachments into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Percutaneous Surgical Set with 5mm or 10mm Attachments 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 Percutaneous Surgical Set with 5mm or 10mm Attachments, indicated for the means to penetrate soft tissue to access certain areas of the human abdomen and used to grasp, hold and manipulate tissue, can be classified in class II with the establishment of special controls. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The potential risks and mitigations associated with the device type are summarized in Table 1.

Table 1 - Potential Risks and Mitigations

Identified Risk	Recommended Mitigation Measures
Adverse Tissue Reaction	Biocompatibility Testing
Device Failure	Performance Testing Sterilization and Shelf Life Testing
User Error	Performance Testing Simulated Use Testing Labeling
Abdominal Cavity Damage	Performance Testing Simulated Use Testing Labeling
Infection	Sterilization and Shelf Life Testing

In addition to the general controls of the FD&C Act, the Manual Percutaneous Surgical Set Assembled in the Abdomen is subject to the following special controls: “Class II Special Controls Guidance Document: Manual Percutaneous Surgical Set Assembled in the Abdomen.”

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 Manual Percutaneous Surgical Sets Assembled in the Abdomen they intend to market prior to marketing the device and receive clearance to market from FDA.

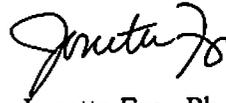
A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for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

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If you have any questions concerning this classification order, please contact Mr. Kareem S. Burney at (301) 796-6388.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jonette Foy".

Jonette Foy, Ph.D.

Deputy Director

for Science and Regulatory Policy

Office of Device Evaluation

Center for Devices and

Radiological Health