DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

November 6, 2018

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

Re: DEN110016 (K110431)
Percutaneous Surgical Set with 5mm or 10mm Attachments
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 878.4805
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:

This letter corrects our classification orders dated April 30, 2012 and January 22, 2018.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Percutaneous Surgical Set with 5mm or 10mm Attachments, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> The Percutaneous Surgical Set with 5 mm or 10 mm Attachments 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 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 manual percutaneous surgical set assembled in the abdomen is a prescription device consisting of a percutaneous surgical set used as a means to penetrate soft tissue to access certain areas of the abdomen. The device's 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 Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 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 received your De Novo requesting classification of the Percutaneous Surgical Set with 5mm or 10mm Attachments into class II. The request 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 De Novo request, 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. FDA believes that class II (special) controls provide

reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Device failure	Non-clinical performance testing, Sterilization validation, and Shelf life testing
User error	Non-clinical performance testing, Simulated use testing, and Labeling
Abdominal cavity damage	Non-clinical performance testing, Simulated use testing, and Labeling
Infection	Sterilization validation, and Shelf life testing

In combination with the general controls of the FD&C Act, the manual percutaneous surgical set assembled in the abdomen is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Performance data must demonstrate the sterility of patient-contacting components of the device.

3. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

4. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   a. Dimensional verification testing must be conducted.
   b. Force verification testing must be conducted. The force testing must demonstrate the forces necessary to insert and operate each component of the device during use as intended.
   c. Functional verification testing of the device components must be conducted.

5. Simulated use testing in an anatomically relevant animal model must demonstrate the device's ability to penetrate soft tissue, be assembled *in situ*, and to grasp, hold and manipulate soft tissues in the intended treatment area.

6. The labeling must include the following:
   a. Instructions for use, including detailed instructions for instrument assembly, disassembly, and removal.
   b. A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

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 request, 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 Cal Rabang, Ph.D. at (301) 796-6412.

Sincerely,

Angela C. Krueger -S FDA

Angela C. Krueger
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health