



December 22, 2017

Ovesco Endoscopy AG
% Martina Krautwald
Consultant
Dorfackerstrasse 26
Tuebingen, Baden-Wuerttemberg
Germany

Re: DEN160014

Trade/Device Name: remOVE System
Regulation Number: 21 CFR 876.4310
Regulation Name: Endoscopic electrosurgical clip cutting system.
Regulatory Class: Class II
Product Code: QAG
Dated: April 4, 2016
Received: April 11, 2016

Dear Martina Krautwald:

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 remOVE System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The remOVE System consists of the DC Impulse and the DC Cutter Set.

The remOVE DC Impulse is a medical electrical device for fragmentation of OTSC® (endoscopic device for effective treatment of hemorrhage and acute or chronic wall defects in the GI tract) and FTRD® (endoscopic device for full-thickness resection of colorectal wall lesions) clips made by Ovesco Endoscopy AG for the digestive tract.

The remOVE DC Cutter Set is a set of instruments for use in flexible endoscopy. It consists of a bipolar DC instrument for the fragmentation of OTSC (endoscopic device for effective treatment of hemorrhage and acute or chronic wall defects in the GI tract) and FTRD (endoscopic device for full-thickness resection of colorectal wall lesion) clips from Ovesco Endoscopy AG, a pair of forceps and a cap for removal of these fragmented clips.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the remOVE System, and substantially equivalent devices of this generic type, into Class II under the generic name Endoscopic electrosurgical clip cutting system.

FDA identifies this generic type of device as:

Endoscopic electrosurgical clip cutting system. An endoscopic electrosurgical clip cutting system is a prescription device that applies electrical energy to fragment metallic clips, which are devices placed in the digestive tract to close gastrointestinal perforations, hemorrhages, or perform resection. The system includes instruments that are then used to remove the fragmented clips from the digestive tract.

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 request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. 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.

On April 11, 2016, FDA received your De Novo requesting classification of the remOVE System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the remOVE 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 De Novo request and through the interactive reviews, FDA has determined that, for the previously stated indications for use, the remOVE System 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. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Unintended tissue damage (burns, perforations, bleeding)	<ul style="list-style-type: none"> • Animal performance testing • Non-clinical performance testing • Electrical and thermal safety testing • Usability testing • Labeling
Electromagnetic interference / Electrical shock	<ul style="list-style-type: none"> • Electromagnetic compatibility testing • Electrical safety testing • Labeling
Adverse tissue reaction	<ul style="list-style-type: none"> • Biocompatibility evaluation
Infection	<ul style="list-style-type: none"> • Sterilization validation • Shelf life testing • Labeling

In combination with the general controls of the FD&C Act, the Endoscopic electrosurgical clip cutting system is subject to the following special controls:

1. 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. Performance bench testing to evaluate the functionality (including stress, compatibility, usability, and reliability) of the device during use.
 - b. Electrical and thermal safety testing
 - c. Electromagnetic compatibility testing
2. Animal testing must evaluate tissue damage, including thermal effects, during the clip removal procedure. This testing must also evaluate usability and effectiveness of the device.
3. The patient-contacting components of the device must be demonstrated to be biocompatible.
4. Performance data must demonstrate the sterility of the device components intended to be provided sterile.
5. Performance data must support shelf life by demonstrating continued sterility of the device (or the sterile components), package integrity, and device functionality over the labeled shelf life.
6. Labeling of the device must include:
 - a. Instructions for use.
 - b. A shelf life for single use components.

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 endoscopic electrosurgical clip cutting system they intend to market prior to marketing the device.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Purva Pandya at 240-402-9979.

Sincerely,

Angela Krueger
Deputy Dir., Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health