



Food and Drug Administration  
10903 New Hampshire Avenue  
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October 12, 2016

Ovesco Endoscopy AG  
% Ms. Martina Krautwald  
Novineon CRO & Consulting Ltd  
Dorfackerstrasse 26  
Tuebingen, Baden-Wuerttemberg 72074 Germany

Re: K153550

Trade/Device Name: DTC Snare  
Regulation Number: 21 CFR 876.4400  
Regulation Name: Hemorrhoidal ligator  
Regulatory Class: Class II  
Product Code: PKL  
Dated: September 9, 2016  
Received: September 12, 2016

Dear Ms. Krautwald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K153550

Device Name  
DTC Snare  
(Set contains DTC Snare, Marking Probe and Grasper)

### Indications for Use (Describe)

#### DTC Snare:

The DTC Snare is indicated for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for haemostasis or for treating lesions of the wall of gastrointestinal organs. Marking of lesions.

The clip is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:

- Endoscopic marking
- Hemostasis for:
  - Mucosal/submucosal defects < 3 cm
  - Bleeding ulcers
  - Arteries < 2 mm
  - Polyps < 1.5 cm in diameter
  - Diverticula in the colon
- Closure of GI tract luminal perforations < 20 mm that can be treated conservatively

The snare is an instrument for flexible endoscopy for grasping and removing tissue in the gastrointestinal tract.

#### Marking Probe:

Instrument for marking tissue using superficial HF coagulation in flexible endoscopy.

#### Grasper:

Instrument for flexible endoscopy for grasping and manipulation of tissue in the gastrointestinal tract, e.g. during interventions with the DTC Snare.

### Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

#### **\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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