SECTION VII.

510(k) Summary of Safety and Effectiveness Information

A. Submitter Information:
   
   Applicant: OVESCO Endoscopy AG
   Dorfackerstrasse 26
   72074 Tuebingen-Germany
   
   Phone Number: +49 7071 - 770 45 - 14
   Fax Number: +49 7071 - 76 35 - 74
   Contact Person: Prof. Dr. Marc O. Schurr,
       Member of the Executive Board
   
   Date of Preparation: May 17, 2010

B. Device Name:
   
   Trade Name: OTSC™ (Over-The-Scope-Clip) System Set
   Dorfackerstrasse 26
   72074 Tuebingen-Germany
   
   Common/Usual Name: Ligator, Hemorrhoidal
   
   Classification Name: Ligator, Hemorrhoidal
   876.4400; 876.1500; 876.5130

C. Predicate Devices:
   
   Trade Name: Speedband Multiple Ligator (K981669 and K020824)
   
   Trade Name: Resolution Hemostasis Clipping Device (K040148)
   
   Trade Name: InScope Multi-Clip Applier (K051950)
D. Device Description:

The OTSC System Set is a single-use, pre-loaded mechanical clip and delivery system used for endoscopic clipping.

E. Intended Use:

The OTSC system set 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 OTSC 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

F. Technological Characteristics Summary:

The OTSC system set is substantially equivalent to the predicates, as they have similar technological characteristics. The results of performance testing show no new issues of safety or effectiveness.
G. Performance Testing

The Resolution Hemostasis Clipping Device (predicate device) and the OTSC system set were compared during a simulated deployment test to ensure that the device can be deployed endoscopically to the target tissue in the correct location. The test series resulted delivered identical results. Both devices can be accurately deployed to the target site.

The force required to dislodge the endoscopic clips from the tissue was measured and compared for the Resolution Hemostasis Clipping Device and the OTSC clip. The dislodgement force of the Resolution Hemostasis Clip and the OTSC clip were comparable and suitable for the intended use.

It can be concluded that the Resolution Hemostasis Clipping Device and the OTSC system set are substantial equivalent in overall performance.
H. Performance Standards

The OTSC System Set meets the following Performance Standards:

<table>
<thead>
<tr>
<th>FDA Recognition Number</th>
<th>Standards No.</th>
<th>Standards Organization</th>
<th>Standards Title</th>
<th>Version</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td>Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995 (FDA Blue Book Memorandum #G95-1)</td>
<td>1995</td>
<td>May 1, 1995</td>
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<tr>
<td>2-117</td>
<td>10993-3</td>
<td>ISO</td>
<td>Tests for genotoxicity, carcinogenicity and reproductive toxicity</td>
<td>2003</td>
<td>2003</td>
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<td>14-76</td>
<td>10993-7</td>
<td>ISO</td>
<td>Biological evaluation of medical devices -- Part 7: Ethylene Oxide Sterilization Residuals</td>
<td>2008</td>
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<td>2-152</td>
<td>10993-10</td>
<td>ISO</td>
<td>Tests for irritation and delayed-type hypersensitivity</td>
<td>2007</td>
<td>2007</td>
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¹ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/CFSearch.cfm
### OTSC™ Over-The-Scope-Clipping System Set
Including the OTSC™Reloader
Traditional Premarket Notification [510(k)]
Ovesco Endoscopy AG

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<th>FDA Recognition Number</th>
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<tr>
<td></td>
<td>868-5</td>
<td>EN</td>
<td>Packaging For Terminally Sterilized Medical Devices - Part 5: Sealable Pouches And Reels Of Porous Materials And Plastic Film Construction - Requirements And Test Methods</td>
<td>2002</td>
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### STERILIZATION:

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<th>FDA Recognition Number</th>
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<td></td>
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<td></td>
<td>Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA</td>
<td>2002</td>
<td>August 30, 2002</td>
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### Standards Table

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<th>FDA Recognition Number</th>
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<td></td>
<td>F2063 - 05</td>
<td>ASTM</td>
<td>Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants</td>
<td>2005</td>
<td>2005</td>
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</table>
I. Substantial Equivalence:

FDA's "Guidance for the Content of Premarket Notifications", and the results of technological characteristics and functional testing support the determination of substantial equivalence for the new device when compared to the predicate devices. The OTSC system set is substantially equivalent to the predicate devices.
March 25, 2015

VISAMED GmbH
Arne Briest
CEO
Kastellstr, 8
D-76227 Karlsruhe
Germany

Re: K101428
Trade/Device Name: OTSC™ (Over-The-Scope-Clip) System Set
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): October 22, 2010
Received (Date on orig SE ltr): October 25, 2010

Dear Arne Briest,

This letter corrects our substantially equivalent letter of December 1, 2010.

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
SECTION I-E.

Statement of Indications for Use

510(k) Number: K101428

Device Name: OTSC™ (Over-The-Scope-Clip) System Set

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDHR Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101428