SECTION VII.

DEC 1 2010

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:

FDA [1]Recognition Number	Standards No.	Standards Organization	Standards Title	Version	Date
BIOCOMPATIBILITY:					
2-98	10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009	2009
-	-	-	**Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995 (FDA Blue Book Memorandum #G95-1)**	1995	May 1, 1995
2-117	10993-3	ISO	**Tests for genotoxicity, carcinogenicity and reproductive toxicity**	2003	2003
2-153	10993-5	ISO	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	2009	2009
2-120	10993-6	ISO	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	2007	2007
14-76	10993-7	ISO	Biological evaluation of medical devices -- Part 7: Ethylene Oxide Sterilization Residuals	2008	2008
2-152	10993-10	ISO	Tests for irritation and delayed-type hypersensitivity	2007	2007
2-135	10993-12	ISO	Sample preparation and reference materials	2007	2007

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

FDA Recognition Number	Standards No.	Standards Organization	Standards Title	Version	Date
GENERAL HOSPITAL:					
14-193	11607-1	ISO	Packaging of terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier systems and packaging-First edition	2006	2006
14-194	11607-2	ISO	Packaging of terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly processes	2006	2006
-	868-5	EN	Packaging For Terminally Sterilized Medical Devices - Part 5: Sealable Pouches And Reels Of Porous Materials And Plastic Film Construction - Requirements And Test Methods	2002	2002
5-40	14971	ISO	Medical devices – Application of Risk Management to Medical Devices + ISO14971:2000/Amd 1:2003	2007	2007
STERILIZATION:					
14-228	11135	ISO	Medical Devices – Validation and routine control of ethylene oxide sterilization ISO 11135:1994/Cor 1:1994	2007	2007
-	-	-	Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA	2002	August 30, 2002
14-229	F 1980-02	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages Sterilization of health care products – Requirements of validation and routine control – Radiation sterilization	2007	2007
14-64	F 1929-98	ASTM	Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	2004	2004

FDA Recognition Number	Standards No.	Standards Organization	Standards Title	Version	Date
			OTHER:		
8-176	F2503-08	ASTM	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonace Enviroment. (Materials)	2008	2008
-	F2063 - 05	ASTM	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	2005	2005
-	-	-	Guidance for Industry and FDA Staff Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment	2008	August 21, 2008
8-124	F2052-02	ASTM	Standard Test Method or Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	2002	2002
8-71	F2182-02a	ASTM	Standard Test Method for Measurement of Radio Frequency Induced Heating Near Implants During Magnetic Resonance Imaging	2002	2002
8-128	F2213-04	ASTM	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	2004	2004
8-153	F2119-01	ASTM	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	2001	2001

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.

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

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" (21CFR 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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- Closure of GI tract luminal perforations < 20 mm that can be treated conservatively

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101428