



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.
Kimberly Shoemaker, RAC
Manager, Regulatory Affairs
4545 Creek Road
Cincinnati, OH 45242-2839

JUL 27 2015

Re: K051950
Trade/Device Name: InScope™ Multi-Clip Applier
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: MND, FHN, OCW, HBT and MCH
Dated (Date on orig SE ltr): September 23, 2005
Received (Date on orig SE ltr): September 26, 2005

Dear Ms. Shoemaker,

This letter corrects our substantially equivalent letter of October 7, 2005.

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,

Benjamin R. Fisher -S

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

K 051950

Indications for Use

510(k) Number (if known): K051950

Device Name: InScope™ Multi-Clip Applier

Indications for Use:

The InScope Multi-Clip Applier is indicated for use with an endoscope to place clips in the gastrointestinal (GI) tract for the purpose of:

- Endoscopic marking,
- Hemostasis for:
 - Mucosal and submucosal defects < 3 cm
 - Bleeding ulcers
 - Arteries < 2 mm
 - Polyps < 1.5 cm in diameter
 - Diverticula in the colon
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
- Closure of GI tract luminal perforations < 20 mm in patients where an alternative to surgery is required.

Prescription Use X
(Part 21 CFR 801 Subpart
D)

AND/OR

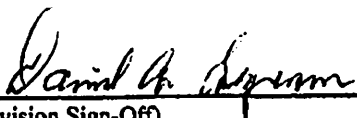
Over-The-Counter Use

(21 CFR 801 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051950

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InScope™ Multi-Clip Applier
510(k) Summary of Safety and Effectiveness

Company

INSCOPE

A Division of Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact

Kimberly Shoemaker, RAC
Manager, Regulatory Affairs

Date Prepared:

July 15, 2005

Name of Device

Trade Name: InScope™ Multi-Clip Applier

Classification Name: Clip Applier/Endoscopic Clipping Device

Predicate Devices:

Trade Name:

Syntheon, LLC: Endoscopic Multi-Fire Clip Applier

Olympus Optical Co., Ltd.: Rotatable Clip Fixing Device HX-5/6-1

Device Description

The InScope™ Multi-Clip Applier is a sterile, single patient use, disposable instrument capable of attaching clips to the mucosal lining of the gastrointestinal (GI) tract. The clips are used to create hemostasis and/or tissue approximation. The distal, flexible portion of the applier is designed to work with a flexible endoscope having a minimum working channel diameter of 3.2 mm. Two opposing jaws grasp tissue via a manually activated lever on a proximal handle. Once the closure lever is latched, a firing mechanism is manually activated, which deploys a titanium clip over the target tissue. The device is supplied preloaded with four (4) titanium clips.

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 - Arteries < 2 mm
 - Polyps < 1.5 cm in diameter
 - Diverticula in the colon
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
- Closure of GI tract luminal perforations < 20 mm in patients where an alternative to surgery is required.

Technological Characteristics

The InScope™ Multi-Clip Applier does not have the identical indication statements as the predicate devices, but the differences noted do not alter the intended therapeutic/diagnostic effect.

Performance Data

Results of bench and preclinical testing demonstrate that performance of the InScope Multi-Fire Clip Applier is substantially equivalent to the predicate devices in regards to hemostasis, clip retention and lack of tissue damage upon clip placement (tissue remains viable).

A literature review in combination with the preclinical data demonstrates the use of the InScope Multi-Clip Applier for closure of gastrointestinal perforations, fistulas, anastomotic leaks and for control of bleeding diverticula is not likely to raise any new or increased risks to safety and effectiveness compared to risks experienced with similar marketed devices.