K110699

MAR 25 2011

510(k) Summary

Company
Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact
Emily Kruetzkamp, Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc
Telephone: (513) 337-1546
Fax: (513) 337-2802
Email: ekruetzk@its.jnj.com

Date Prepared: March 9, 2011

Device Name
Trade Name: Ligamax™ 5
Common Name: Clip Applier

Classification Names
Implantable Clip

Predicate Device
Ligamax™ 5, a 5 MM Endoscopic Multiple Clip Applier, cleared under K050344 on March 14, 2005 as Ligaclip 5 M/L

Device Description:

The Ethicon Endo-Surgery Ligamax 5 is a 5 mm endoscopic multiple clip applier. This sterile, single patient use, instrument is designed to provide a means of ligation on tubular structures or vessels through an appropriately-sized trocar. The instrument contains 15 medium-large titanium clips for occluding tissue, structures, and vessels.

Indication for Use:

The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

Technological Characteristics:

The instrument configuration consists of a pistol handle portion, an actuation trigger, a rotation knob, and a shaft with an outer diameter of 5.5 mm and length of 33 cm. The shaft contains an etched line of demarcation, which aids the user's visualization when the device is adequately inserted through the trocar. At the distal end of the shaft are the jaws, which form ligating clips. The force to squeeze the trigger increases when there are no clips remaining in the device, this is known as the tactile last-clip lockout indicator.

Performance Data: Bench testing was performed to demonstrate that the device will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Ms. Emily Kruetzkamp
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

MAR 25 2011

Re: K110699
Trade/Device Name: Ligamax™ 5
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: March 10, 2011
Received: March 14, 2011

Dear Ms. Kruetzkamp:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K110699

Device Name: Ligamax™ 5

Indications for Use:

The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

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)

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(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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