DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 10, 2015

Ethicon Endo-Surgery, LLC
% Ms. Emily Kruetzkamp
Ethicon Endo-Surgery, Incorporated
4545 Creek Road
Cincinnati, Ohio 45245

Re: K150840
Trade/Device Name: LIGACLIP 10mm M/L Endoscopic Rotating Multiple Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: August 7, 2015
Received: August 11, 2015

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 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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150840

Device Name
LIGACLIP 10mm M/L Endoscopic Rotating Multiple Clip Applier

Indications for Use *(Describe)*
The Ligaclip® Endoscopic Rotating Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

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.

510(k) Summary

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

Contact
Emily Kruetzkamp, Manger, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
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Email: ekruetzk@its.jnj.com

Date Prepared:	March 26, 2015
Trade Name:	Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier
Common Name:	Clip Applier
Classification Name:	Clip, Implantable
Device Class:	Class II
Classification Regulation:	878.4300
Panel:	79, General and Plastic Surgery
Classification Code:	FZP
Predicate Device	Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier submitted as Ligaclip® 20/20 Multiple Clip Applier, K864102
Reference Device	Ligamax™ 5, K110699

Device Description
The Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier is a sterile, single-patient use device, designed to provide a means of ligation on tubular structures or vessels through an appropriately-sized trocar. The device contains 20 medium-large titanium clips that individually advance after each firing. The device shaft rotates 360˚ in either direction. The rotating knob is located on the handle to allow for a one-handed technique.

Indications for Use
The Ligaclip Endoscopic Rotating Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Technological Characteristics
The instrument configuration consists of a pistol handle, a rotation knob, and a shaft with an outer diameter of approximately 10 mm and length of 28.9 cm. The shaft is made of a low glare material that minimizes reflective distortion. At the distal end of the shaft are the jaws, which form ligating clips. The force to squeeze the trigger increases when no clips remain in the device. The shaft contains a yellow clip counter indicator bar, which appears yellow when only 3 clips or fewer remain in the device.

Performance Data

Ex-vivo tests were performed to verify that the performance of the Subject Device, Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier instrument, meets the definition of substantial equivalence to the Predicate Device, Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier submitted as Ligaclip® 20/20 Multiple Clip Applier instrument. Device performance was assessed against design requirements. Bench testing includes trocar compatibility, retention strength of unformed clip in jaws, ratchet mechanism strength, ergonomic torque to fire device, tactile indication torque for "no-clip lockout" function, low clip indicator bar performance, clip occlusion of the formed clip, and clip security of the formed clip. Hydrodynamic testing on excised porcine vessels was included to demonstrate clip leak resistance.

Biocompatibility Testing

The biocompatibility evaluation for the Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier device was conducted in accordance with the FDA Blue Book Memorandum #G95- 1 "Use of International Standard ISO-10993,'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Pyrogen Testing was conducted.

The conclusions of the testing criteria demonstrate that the Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier device is substantially equivalent to the legally marketed Predicate Device, K864102.

This submission does not include data from Clinical Studies.