October 30, 2018

Ethicon Endo-Surgery, LLC
% Ms. Melissa Iwu
Senior Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc
4545 Creek Rd
Cincinnati, Ohio 45245

Re: K181488
Trade/Device Name: LIGACLIP 12mm 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 30, 2018
Received: August 31, 2018

Dear Melissa Iwu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph Nielsen -S

Digitally signed by Joseph Nielsen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Joseph Nielsen -S, 0.9.2342.19200300.100.1.1=2000367505
Date: 2018.10.30 08:03:39 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181488

Device Name
LIGACLIP 12mm 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.

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510(k) Summary

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

Contact
Melissa Iwu, Senior Specialist, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
Telephone: 513.337.7623
Email: miwu2@its.jnj.com

Date Prepared:	October 19, 2018
Trade Name:	Ligaclip® 12mm L Endoscopic Rotating Multiple Clip Applier
Common Name:	Clip Applier
Classification Name:	Implantable Clip
Device Class:	Class II
Classification Regulation:	878.4300
Panel:	79, General and Plastic Surgery
Classification Code:	FZP
Primary Predicate Device:	Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier, K150840
Secondary 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® 12mm L Endoscopic Rotating Multiple Clip Applier is a sterile, single-patient use device designed to provide a means of ligation through Endopath surgical trocars. The device delivers 20 large titanium clips that individually advance after each firing. The shaft is made of a low glare material that minimizes reflective distortion. It is designed to rotate 360˚ in either direction. The rotating knob is located 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.

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Technological Characteristics

The Subject Device, Ligaclip® 12mm L Endoscopic Rotating Multiple Clip Applier's configuration consists of a pistol handle, a rotation knob, and a shaft with an outer diameter of approximately 11.84 mm and length of 34.1 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.

The Subject Device is comprised of the same technological characteristics as the Primary Predicate Device with respect to materials, design, energy source, and other features. The key differences between the two devices are the working shaft length (28.9 cm for Primary Predicate, and 34.1 cm for Subject), trocar sizes (10/11 mm for Primary Predicate and 12 mm for Subject), and closed clip length (8.8 mm for Primary Predicate and 11.0 mm for Subject). The clip continues to ligate tubular structures and vessels and the clip formation remains unchanged.

Performance Data

Ex-vivo tests were performed to verify that the performance of the Subject Device, Ligaclip® 12mm L Endoscopic Rotating Multiple Clip Applier, meets the definition of substantial equivalence to the Primary Predicate Device, Ligaclip® 10mm M/L Endoscopic Rotating Multiple Clip Applier. Device performance was assessed against the Subject Device's design requirement and comparative testing against the Primary and Secondary Predicate Devices. 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. Product Stability and Biocompatibility data from the Primary Predicate Device was leveraged in this submission as the Subject and Primary Predicate Device materials remain unchanged. Data from Pre-Clinical studies, specifically rabbit pyrogenicity and limulus amoebocyte lysate (LAL) testing, was included in the submission. This submission does not contain data from Clinical studies.

The conclusions of the testing criteria demonstrate that the Ligaclip® 12mm L Endoscopic Rotating Multiple Clip Applier device is substantially equivalent to the legally marketed Primary Predicate Device, K150840, and Secondary Predicate Device, K864102.