August 29, 2023

Ethicon Endo Surgery, LLC.
Lakrisha Tinner
Manager, Regulatory Affairs
475 Calle C
Guaynabo, 00969
Puerto Rico

Re: K232313
Trade/Device Name: LIGACLIP Endoscopic Rotating Multiple Clip Applier 12mm L (ER420);
LIGACLIP Endoscopic Rotating Multiple Clip Applier 10mm M/L (ER320)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: August 1, 2023
Received: August 2, 2023

Dear Lakrisha Tinner:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.08.29 23:01:31 -04'00'

Tek Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232313

Device Name

LIGACLIP Endoscopic Rotating Multiple Clip Applier 12mm L (ER420);
LIGACLIP Endoscopic Rotating Multiple Clip Applier 10mm M/L (ER320)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K232313 510(k) Summary

Prepared on: 2023-08-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ethicon Endo Surgery, LLC.
Applicant Address	475 Calle C Guaynabo 00969 Puerto Rico
Applicant Contact Telephone	(517) 337-7475
Applicant Contact	Mrs. Lakrisha Tinner
Applicant Contact Email	LTinner1@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LIGACLIP Endoscopic Rotating Multiple Clip Applier 12mm L (ER420); LIGACLIP Endoscopic Rotating Multiple Clip Applier 10mm M/L (ER320)
Common Name	Implantable clip
Classification Name	Clip, Implantable
Regulation Number	878.4300
Product Code	FZP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181488	LIGACLIP 12mm L Endoscopic Rotating Multiple Clip Applier	FZP
K150840	LIGACLIP 10mm M/L Endoscopic Rotating Multiple Clip Applier	FZP

Device Description Summary

21 CFR 807.92(a)(4)

The LIGACLIP 12mm L and 10mm M/L Endoscopic Rotating Clip Appliers are sterile, single-patient use instruments designed to provide a means of ligation through surgical trocars. The instruments deliver titanium clips that individually advance after each firing. The shafts of these devices are made of a low glare material that minimizes reflective distortion. The are designed to rotate 360 degrees in either direction.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical to the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject devices, LIGACLIP 12mm L and 10mm M/L Endoscopic Rotating Multiple Clip Applier instruments, are substantially equivalent to the predicate Ligaclip® 12mm L and 10mm M/L Rotating Multiple Clip Applier instruments. The only technological

difference between the Subject and Predicate device is a minor dimensional change to an internal component of the device. The changes described in this submission do not affect the intended use of the device, nor do they alter the fundamental scientific technology of the device. The subject devices share the same technological characteristics with respect to materials, design, energy source, and principles of operation as the predicate devices. The Subject devices have similar dimensional characteristics compared to the Predicate. The clip continues to ligate tubular structures and vessels and the clip formation is unchanged. The configuration of the Subject devices, Ligaclip® 12mm L and 10mm M/L Endoscopic Rotating Multiple Clip Appliers consist of a pistol handle, a rotation knob, and a shaft. 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.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

A usability study was conducted to evaluate the ease-of-use of the added steps to the Instructions for Use. The usability testing conducted to evaluate the usability and acceptance of the updated language in the IFU met the success criteria. The usability study demonstrated that the evaluated IFU steps can be performed as intended by representative users without a pattern of use error, close calls or use difficulty.

Verification testing for the minor component design change was conducted to demonstrate acceptable device functionality performance of the subject device and to ensure the device continues to meet the existing finished good specification of the predicate device. The verification testing conducted to evaluate the change to the device component met the success criteria.

The conclusions drawn from the non-clinical tests demonstrate that the subject device, LIGACLIP Endoscopic Rotating Multiple Clip Applier 12mm L (ER420);LIGACLIP Endoscopic Rotating Multiple Clip Applier 10mm M/L (ER320) (K232313), is as safe, as effective, and performs as well as the legally marketed predicate devices, K181488 and K150840.