DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 3, 2016

Ethicon Endo-Surgery, Inc.
Ms. Rubina Dosani, M.S.
Sr. Regulatory Affairs Project Lead
4545 Creek Road
Cincinnati, OH 45242

Re: K153611
Trade/Device Name: Coated VICRYL (Polyglactin 910)Sterile Synthetic Absorbable Suture Cartridges, ETHIBOND Polybutilate Coated Polyester Sterile Synthetic Non-Absorbable Suture Cartridges, PROXISURE Suturing Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM, GAT, OCW
Dated: May 3, 2016
Received: May 5, 2016

Dear Ms. Dosani:

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 Parts 801 and 809); 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)*
K153611

Device Name
PROXISURE™ Suturing Device
ETHIBOND™ Suture Cartridge
Coated VICRYL™ Suture Cartridge

Indications for Use *(Describe)*
The PROXISURE™ Suturing Device, ETHIBOND™ Suture Cartridge, and Coated VICRYL™ Suture Cartridge are indicated for suturing in minimally invasive surgeries. Applications are for the placement of interrupted or running stitches in soft tissue.

The PROXISURE™ Suturing Device and ETHIBOND™ Suture Cartridge are indicated for suturing in minimally invasive surgeries. Applications are for the placement of interrupted or running stitches in soft tissue.

The PROXISURE™ Suturing Device and Coated VICRYL™ Suture Cartridge are indicated for suturing in minimally invasive surgeries. Applications are for the placement of interrupted or running stitches in soft tissue.

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

Submitter Information: Ethicon, LLC
475 C Street
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Application Correspondent
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Date Prepared December 16, 2015

PROXISURE™ Suturing System which includes the following components: PROXISURE™ Suturing Device, Coated VICRYL™ Suture Cartridge, ETHIBOND™ Suture Cartridge.

Device Trade Name:	PROXISURE™ Suturing Device
Device Common Name:	Endoscopic Suturing Device
Classification Regulation:	21 CFR 876.1500
Device Class:	II
Panel:	General & Plastic Surgery
Product Code:	OCW

Device Trade Name:	Coated VICRYL™ Suture Cartridge
Device Common Name:	Suture, Absorbable, Synthetic, Polyglycolic Acid
Classification Regulation:	21 CFR 878.4493
Device Class:	II
Panel:	General & Plastic Surgery
Product Code:	GAM

Device Trade Name:	ETHIBOND™ Suture Cartridge
Device Common Name:	Suture, Non-Absorbable, Synthetic, Polyethylene
Classification Regulation:	21 CFR 878.5000
Device Class:	II
Panel:	General & Plastic Surgery
Product Code:	GAT

Predicate Devices:	Modified Endo Stitch™ (K082659) Coated VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Suture (K022269) ETHIBOND EXCEL™ Polybutlylate Coated Polyester Sterile Synthetic Non-Absorbable Suture (K946173)

Device Description

The PROXISURE™ Suturing System is composed of a reusable PROXISURE™ Suturing Device and single-use, sterile Suture Cartridges that are used for placement of interrupted or running stitches in soft tissue. The Suturing Device has a stationary shaft that has an articulating and rotating end effector. The device is reusable and must be cleaned and sterilized by the end user per the cleaning, disinfection, and sterilization instructions provided in the Instructions for Use before and between uses. A Suture Cartridge is loaded at the distal tip of the end effector which contains the needle and suture for use during the surgical procedures.

The PROXISURE ™ Suture Cartridges are designed for use with the PROXISURE™ Suturing Device and are available with two types of sutures in three sizes each. The suture material is commercially available Coated VICRYL™ and ETHIBOND EXCEL™ sutures. ETHIBOND™ Suture is dyed green with D&C Green #6 (Color Index No. 61565) to enhance visibility in the surgical field. ETHIBOND Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for sterile poly(ethylene terephthalate) Suture and the United States Pharmacopoeia (USP) for Non-Absorbable Surgical Sutures. Coated VICRYL™ Sutures that come with the Suture Cartridge are dyed by adding D+C violet #2 (Color Index number: 60725) during polymerization. Coated VICRYL™ Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopoeia (USP) for Sterile Synthetic Absorbable Braided Sutures, except for an occasional slight oversize in the gauges for the suture cartridge. The PROXISURE™ Suturing Device and the Suture Cartridges are packaged separately and will be available for assembly prior to use at the surgical site.

Indications for Use for the components of the PROXISURE™ Suturing System

The PROXISURE™ Suturing Device, ETHIBOND™ Suture Cartridge and Coated VICRYL™ Suture Cartridge are indicated for suturing in minimally invasive surgeries. Applications are for the placement of interrupted or running stitches in soft tissue.

The PROXISURE™ Suturing Device and ETHIBOND™ Suture Cartridge are indicated for suturing in minimally invasive surgeries. Applications are for the placement of interrupted or running stitches in soft tissue.

The PROXISURE™ Suturing Device and Coated VICRYL™ Suture Cartridge are indicated for suturing in minimally invasive surgeries. Applications are for the placement of interrupted or running stitches in soft tissue.

Substantial Equivalence Summary

The subject and predicate devices have the same intended use and primary surgical use - suturing in minimally invasive surgeries with applications for the placement of interrupted or running stitches in soft tissue. Both subject and predicate devices are mechanical devices where no energy passes through to the patient, are not battery operated and do not use software.

Technological Characteristics

The suturing device is composed of a reusable handle and shaft with a rotating and articulating distal end effector. The working length of the suturing device is 40 cm with a 12mm diameter which will fit through a 12mm trocar. A single-use, sterile Suture Cartridge is loaded at the distal tip of the end effector containing the needle and suture for use during surgical procedures.

Performance Data

Bench testing was performed to verify the performance of the subject device meets the definition of substantial equivalence to the predicate device and the device will perform as intended. Bench testing included needle passing reliability testing, needle passing and tissue sticking testing, knot strength testing, needle pull off strength, suture manipulation needle release, cartridge cage pull-back, needle release force and end effector features testing.

The conclusions of the testing criteria demonstrate the subject device performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

This submission does not include data from Clinical Studies.