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

March 26, 2015

Ethicon Incorporated
Ms. Susan Lin, RAC
Manager, Regulatory Affairs
P.O. Box 151
Route 22 West
Somerville, New Jersey 08876

Re: K142822
Trade/Device Name: PLIASURE™ Polyglycolide Synthetic Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: February 19, 2015
Received: February 23, 2015

Dear Ms. Lin:

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,

Jennifer R. Stevenson -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)*
K142822

Device Name
PLIASURE™ Polyglycolide Synthetic Absorbable Suture

Indications for Use *(Describe)*
PLIASURE Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular and neurological tissues.

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.

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510(k) Summary

I. SUBMITTER:

Ethicon
P.O. Box 151
Route 22 West
Somerville, NJ 08876
USA
Phone: 918-218-2256
Fax: 918-218-2595

Date: September 29, 2014
Contact Person: Susan Lin

II. DEVICE

Name of Device: PLIASURE™ Polyglycolide Synthetic Absorbable Suture

Common Device Name: Suture, Absorbable, Synthetic, Polyglycolic Acid

Classification Name: Absorbable Poly(glycolide/L-lactide) Surgical Suture

Regulatory Class: Class II, 21 CFR 878.4493

Product Code: GAM

III. PREDICATE DEVICES:

VICRYL™ Coated Suture (K022269)
DEXON/DEXON II Braided Suture (K972566)

IV. DEVICE DESCRIPTION:

PLIASURE Suture is a synthetic absorbable sterile surgical suture composed of the homopolymer of glycolide (PGA). PLIASURE Suture is prepared by coating PGA suture material with a mixture composed of equal parts of copolymer of glycolide and lactide (polyglactin 370) with calcium stearate. The polymers used in this product have been found to be nonpyrogenic and elicit minimal tissue reaction during absorption. The sutures are braided bi-colored with a combination of dyed (D&C Violet #2) and undyed (natural) yarns. PLIASURE Sutures meet U.S.P. for synthetic absorbable sutures except for diameter.

V. INDICATION FOR USE

PLIASURE Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular and neurological tissues.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

PLIASURE Suture has same materials as the predicate devices. Like the currently marketed predicate devices, PLIASURE Suture is a sterile, braided synthetic absorbable suture intended for the soft tissue approximation and/or ligation. It conforms to the USP Monograph for absorbable surgical sutures, except for diameter.

VII. PERFORMANCE DATA

Non-clinical testing was conducted on the device per FDA's Special Control Guidance Document: Surgical Suture. The following performance data was provided in support of the substantial equivalence determination:

Biocompatibility Evaluation

PLIASURE Suture is considered a permanent (>30 days) tissue contact implant device.

The biocompatibility evaluation for PLIASURE Suture was conducted in accordance with International Standard ISO 10993-1"Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, " as recognized by FDA, and 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. The battery of testing included the following tests:

- Cytotoxicity
- Irritation and Sensitization
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Implantation (for Tissue Reaction and Absorption)

Physical/Performance Characteristics

USP performance testing including Suture – Diameter <861>, Suture – Needle Attachment <871>, and Tensile Strength <881> was conducted on the sterilized suture samples in finished form. Additional performance testing was conducted in order to demonstrate substantial equivalence to the predicate device including in vivo tensile strength retention profile and absorption profile.

VIII. CONCLUSIONS

PLIASURE Suture has the same intended use as the predicate devices. The main technological characteristics of PLIASURE Suture are the same as the predicate devices. The performance data including biocompatibility testing, physical performance testing, and in vivo evaluation of tensile strength and absorption profile demonstrate that PLIASURE Suture is substantially equivalent to the predicate devices.