June 27, 2019

Ethicon, Inc.
Ms. Stephanie Saati
Sr. Regulatory Affairs Program Lead
Route 22 West P.O. Box 151
Somerville, New Jersey 08876

Re: K183183
Trade/Device Name: VICRYL™ Polyglactin 910 Sterile Synthetic Absorbable Surgical Suture
PDS™ II (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, NEW
Dated: May 23, 2019
Received: May 24, 2019

Dear Ms. Saati:

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,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183183

Device Name
VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture
PDS™ II (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture

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

PDS™ II Suture is indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDS™ II Suture is not indicated in adult cardiovascular tissue and neurological tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.

PDS™ Plus Suture is indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery (other than contact with cornea and sclera). PDS™ Plus Suture is not indicated in adult cardiovascular tissue and neurological tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.

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: Ethicon, Inc. a Johnson & Johnson company
P.O. Box 151
Route 22 West
Somerville, NJ 08876-0151

Contact Person: Stephanie Saati
Senior Regulatory Affairs Program Lead
Phone: 908-218-3318
Fax: 908-218-2595
Email: ssaati@its.jnj.com

Date Prepared: May 20, 2019

Device Trade Name:	VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture
Common Name:	Suture, Absorbable, Synthetic, Polyglycolic Acid
Regulatory Classification:	Absorbable poly(glycolide/l-lactide) surgical suture (21 CFR 878.4493
Class:	II
Code:	GAM
Panel:	General and Plastic Surgery Devices

Device Trade Name:	PDS™ II (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
Common Name:	Suture, Surgical, Absorbable, Polydioxanone
Regulatory Classification:	Absorbable Polydioxanone Surgical Suture (21 CFR 878.4840)
Class:	II
Product Code:	NEW
Panel:	General and Plastic Surgery Devices

Device Trade Name:	PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
Common Name:	Suture, Surgical, Absorbable, Polydioxanone
Regulatory Classification:	Absorbable Polydioxanone Surgical Suture (21 CFR 878.4840)
Class:	II
Product Code:	NEW
Panel:	General and Plastic Surgery Devices

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Predicate Devices:

Device	Company	Product Code	510(k)/ NDA Number
VICRYL™ (Polyglactin 910) Braided Coated and Uncoated Synthetic Absorbable Suture, Dyed & Undyed, Braided and Monofilament	Ethicon, Inc.	GAM	K946271
PDS™ II (Polydioxanone) Suture Dyed & Undyed	Ethicon, Inc.	NEW	N18331
PDS™ Plus Antibacterial Suture	Ethicon, Inc.	NEW	K061037

Device Description:

VICRYL™ (Polyglactin 910) Suture is a sterile, synthetic, absorbable, surgical suture composed of a copolymer made of 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$. VICRYL™ Suture is available as a coated or an uncoated suture.

VICRYL™ Suture is coated with a mixture composed of equal parts of copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. Polyglactin 910 copolymer and Polyglactin 370 with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

VICRYL™ Suture is available undyed and dyed with D&C Violet #2 (Color Index 60725) to enhance visibility in the surgical field.

VICRYL™ Suture is available in a range of gauge sizes and lengths, types and sizes, and in presentations non-needled or attached to needles of various types and sizes.

PDS™ II (Polydioxanone) Suture is a sterile, synthetic, absorbable, surgical monofilament suture prepared from the polyester, poly(p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$. Polydioxanone polymer has been found to be nonallergenic, nonpyrogenic, and elicits only a slight tissue reaction during absorption.

PDS™ II Suture is available undyed and dyed with D&C Violet Number 2 (Color Index 60725) to enhance visibility in the surgical field.

PDS™ II Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of various types and sizes.

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PDS™ Plus Antibacterial (Polydioxanone) Suture is a sterile, synthetic, absorbable, surgical monofilament suture made from the polyester poly(p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$. Polydioxanone polymer has been found to be nonallergenic, nonpyrogenic, and elicits only a slight tissue reaction during absorption.

PDS™ Plus Suture is available undyed and dyed with D&C Violet No. 2 (Color Index 60725) to enhance visibility in the surgical field.

PDS™ Plus Suture contains Irgacare®‡ MP (triclosan), a broad-spectrum antibacterial agent at no more than 2360 µg/m.

PDS™ Plus Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of varying types and sizes.

Indications for Use:

VICRYL™ (Polyglactin 910_ Sterile Synthetic Absorbable Surgical Suture:
VICRYL™ Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissues.

PDS™ II (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture:
PDS™ II Suture is indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDS™ II Suture is not indicated in adult cardiovascular tissue and neurological tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.

PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture:
PDS™ Plus Suture is indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery (other than contact with cornea and sclera). PDS™ Plus Suture is not indicated in adult cardiovascular tissue and neurological tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.

Summary of Technological Characteristics:

The technological characteristics of the subject devices are identical to the predicate devices and performance data are not necessary to establish substantial equivalence.

Substantial Equivalence:

The proposed devices are identical to the predicate devices with respect to functionality, technological characteristics and intended use. There is no material, device construction,

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performance specification, packaging, sterilization or manufacturing process changes to the currently marketed devices. The devices differ only in the labeling (Instructions for Use) which have been revised for clarification, standardization, and harmonization with the intent of creating Instructions for Use which can be supplied globally. There is no change to the intended use or to the patient population for these devices. The proposed devices do not raise new questions of safety or effectiveness as the predicate devices and are therefore substantially equivalent.

Conclusion:

Based on the intended use, fundamental scientific technology, technological characteristics and the intended use, the following subject devices, VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture, PDS™ II (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture, and PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture are considered to be substantially equivalent to their predicated devices.