February 22, 2022

Ethicon, Inc.
Marife Sevek
Sr. Regulatory Affairs Program Lead
1000 Route 202
Raritan, New Jersey 08869

Re: K212380
Trade/Device Name: PDS Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorable Surgical Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: December 17, 2021
Received: December 20, 2021

Dear Marife Sevek:

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 Deborah Fellhauer, RN, BSN
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.

510(k) Number *(if known)*
K212380

Device Name
PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture

Indications for Use *(Describe)*
PDS™ Plus Suture is indicated for use in general soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur. PDS™ Plus Suture is not indicated in adult cardiovascular 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.

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

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ETHICON, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon, Inc., a *Johnson & Johnson* Company
1000 Route 202
Raritan, New Jersey 08869
USA

Contact Person: Marife Sevek
Sr. Regulatory Affairs Program Lead
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Date Prepared: February 14, 2022

Device Trade Name: PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture

Device Common Name: Suture, Surgical, Absorbable, Polydioxanone

Class: II

Classification Name: Absorbable Polydioxanone Surgical Suture
(21 CFR 878.4840)

Product Code: NEW

Predicate Device:

Predicate Device	510(k) Number
PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture	K061037

Device Description:

PDS™ Plus Antibacterial Suture is a sterile synthetic absorbable monofilament suture made from the polyester poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$.

PDS™ Plus Antibacterial Suture is available undyed and dyed with D&C Violet No. 2

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

Indications for Use:

PDS™ Plus Suture is indicated for use in general soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur. PDS™ Plus Suture is not indicated in adult cardiovascular 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 and Performance:

The subject device has the same technological characteristics as the predicate device. Like the currently marketed predicate device, it is a sterile, monofilament synthetic absorbable suture that complies with the requirements of the United States Pharmacopoeia (USP) for absorbable surgical sutures except for a slight oversize in diameter.

Like the currently marketed predicate device, PDS™ Plus Antibacterial Suture, the subject device will continue to be available as a suture product with Irgacare®‡ MP (triclosan), an antibacterial agent.

Using *in vitro* studies, Irgacare®‡ MP (triclosan) in PDS™ *Plus* Antibacterial Suture has been shown to inhibit colonization of the suture by *Staphylococcus aureus*, *Staphylococcus epidermidis*, Methicillin-*resistant S. aureus*, Methicillin-*resistant S. epidermidis*, *Escherichia coli*, and *Klebsiella pneumoniae*, and *Enterobacter cloacae*.

Substantial Equivalence:

The subject device is identical to the predicate device in terms of material, construction, specification, manufacturing, and sterilization process. The subject device and currently marketed device differ only in the labeling (Instruction for Use and device box). The Performance/Actions section in the Instructions for Use of the subject device was revised to include in-*vitro* effectiveness against one an additional microorganism, *Enterobacter cloacae*. This was demonstrated through quantitative *in-vitro* attachment assay which demonstrates efficacy of the antibacterial suture surface to prevent bacterial colonization against *Enterobacter cloacae*. The efficacy is reported as a log difference in attached bacteria between treated and untreated suture controls. Additionally, the Indication statement in the Instructions for Use of the subject device were revised to remove ophthalmic surgery. Minor changes to the package label

of the subject devices also includes a new descriptor and icon to allow customers to easily distinguish between Ethicon PDS™ Suture and Ethicon PDS™ Plus Antibacterial Suture.

Conclusion:

There are no physical or technological characteristic changes to the currently marketed predicate device. The proposed labeling changes for the subject device have been shown to be appropriate for its intended use based on the test result that was submitted. Therefore, the subject device is substantially equivalent to the predicate device.

** Trademark*
Irgacare®‡ MP (triclosan) "Registered Trademark of BASF Group"