November 12, 2025

Ethicon, Inc.
Anju Malhotra
Regulatory Affairs Specialist II
1000 Us-202
Raritan, New Jersey 08869

Re: K243897
Trade/Device Name: PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: November 10, 2025
Received: November 10, 2025

Dear Anju Malhotra:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243897

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.

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

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510(k) Summary (K243897)

Applicant

Ethicon, Inc.
1000 Route 202
Raritan, New Jersey 08869

Contact Person

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Device Name

Device Trade Name: PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
Common Name: Absorbable polydioxanone surgical suture
Classification Name: Suture, Surgical, Absorbable, Polydioxanone
Regulation Number: 878.4840
Product Code(s): NEW

Legally Marketed Predicate Devices

Predicate #: K212380
Predicate Trade Name: PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture
Product Code: GAM

Device Description Summary

PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical 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 (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture is available undyed and dyed with D&C Violet No. 2.

PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture contains Triclosan, a broad spectrum antibacterial agent, ranging between 42 – 2360 µg of

Triclosan per meter of suture. The maximum of 2360 µg/m falls well below literature values for toxicity of Triclosan based on a single worst-case dose.

The lower specification limit is set at a value where claims for in-vitro antibacterial activity can be supported across all product variants throughout their shelf-life.

Intended Use/Indications for Use

PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur. PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical 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.

Indications for Use Comparison

There is no change in indications for use between the predicate and subject devices.

Technological Comparison

Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] has been followed and it was determined that subject PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture is substantially equivalent to the predicate PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture in that they share:

a) the same fundamental scientific technology,
b) the same intended use,
c) the same design,
d) the same materials,
e) equivalent packaging materials and configuration,
f) the same labeling components
g) the same sterilization process (Ethylene Oxide)
h) the same sterility assurance level (SAL) is 10^{-6}.

The subject device has the same technological characteristics as the predicate device. The primary difference between the subject and predicate device is the device packaging – the subject device is available in plastic trays containing a means for Triclosan deposition. The subject device will also be available as a USP Size 2 suture offering.

Non-Clinical and/or clinical Tests Summary and Conclusions

The design verification testing evaluated the subject PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture with Triclosan concentration for each size at the lower specification limit against a control PDS suture (which does not contain Triclosan) of the same size and confirmed that the subject device meets the same requirements for in vitro antibacterial effectiveness as the predicate device. Benchtop performance testing concluded that the subject device meets the design requirement for in vitro antibacterial effectiveness for sizes 2 through 6-0 at the lower Triclosan specification limit.

Breaking strength retention (BSR) was evaluated in vivo for the subject PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture strands in sizes 2, 1, 3-0, and 6-0 at 0, 14, 28 and 42 day time points. In vivo evaluation of breaking strength retention (BSR) concluded that BSR values of the subject PDS™ Plus Antibacterial (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture device met expectations.

Conclusion

In-vivo and in-vitro testing demonstrates that the subject device is substantially equivalent to the currently marketed predicate device.