May 18, 2026

ETHICON, Inc.
Samantha Mecker
Associate Director, Regulatory Affairs
1000 Rte. 202 S.
Raritan, New Jersey 08869

Re: K252047
Trade/Device Name: STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: March 31, 2026
Received: March 31, 2026

Dear Samantha Mecker:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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Infection Control Devices
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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.

510(k) Number *(if known)*
K252047

Device Name
STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices

Indications for Use *(Describe)*
The STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

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 (K252047)

Submitter: Ethicon Inc. a *Johnson & Johnson* company
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Raritan, New Jersey 08869

Contact Person: Samantha Mecker
Ethicon, Inc. a *Johnson & Johnson* company
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Phone: (732) 837-8599

Date Prepared: May 15, 2026

Device Trade Name: STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices

Device Common Name: Suture, Surgical, Absorbable, Polydioxanone

Class: II

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

Product Code: NEW

Legally Marketed Predicate Devices	**510(k) Number**	**Product Code**
STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device	K182873	NEW

Device Description:

STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device is an antibacterial (polydioxanone) monofilament, synthetic absorbable device prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C4H6O3)_x$. The device contains IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 µg/m. STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device is dyed with D&C Violet No. 2.

STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device consists of an absorbable thread with unidirectional anchors, equipped with a surgical needle at one end and a fixation tab at the other. The anchors and fixation tab design allows for tissue approximation without the need to tie surgical knots. Polydioxanone has been found to be nonallergenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

Indications for Use:

The STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

The indications for use are identical between the subject and predicate devices.

Comparison of Technological Characteristics with the Predicate Devices:

The Instructions for Use of the subject devices are updated with the following language to add the on-label use of high tension closure. The subject devices differ from their respective predicate devices only in the Instructions for Use (IFU).

<u>Ethicon will add the following language to the Actions section of the IFU</u>:

The barbs are uniquely designed and provide maximum holding in soft tissue where PDS™ Plus Suture is commonly used, including in high tension areas such as abdominal wall fascia, knee extensor mechanism fascia during a total knee replacement, deep hip fascia used during a total hip replacement, deep lumbar fascia during spine surgery, closure of mini-laparotomy incisions in patients with BMI less than 30 kg/m², and ventral hernia fascial closure with mesh.

As Ethicon adds high tension use specifically on-label in our IFU, Ethicon will also include the following language in the Warnings section of the IFU as additional clarification related to the use in high tension closure in abdominal wall surgery applications:
Safety and effectiveness has not been established in closure of full (>10 cm) laparotomy incisions, or in patients with BMI >30 kg/m^2 and use in these scenarios could result in wound dehiscence or incisional hernia. This should not supersede good clinical judgement.

There are no changes to the technological characteristics of the STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices.

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 Devices are substantially equivalent to the predicate 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.

Performance Data:

A literature review was performed to support update of the STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices labeling to describe high tension closure, inclusive of 25 publications in abdominal procedures and 19 publications in orthopedic procedures. Study endpoints ranged from 30 days to 2 years post procedure. While each paper had different levels of reliability, 96% of the clinical comparison papers (12 studies evaluating abdominal wall procedures and 13 evaluating orthopedic procedures) show similar performance of STRATAFIX Symmetric versus non-barbed sutures.

Additionally, two retrospective observational clinical studies were performed to provide clinical evidence using real-world data from routine clinical practice:

1. A retrospective, single-arm, multi-institution cohort study in the Premier Healthcare Database (PHD) was conducted to evaluate clinical outcomes of the STRATAFIX Symmetric PDS™ Plus Knotless Tissue Control Device for wound closure in high-tension areas in clinical practice, specifically focusing on the incidence of postoperative complications of internal wound dehiscence at 30 days post-index procedure. To contextualize the study findings, a literature review was performed to evaluate the incidence of outcomes of interest in the current study versus prior literature.
2. A second retrospective, comparative cohort study was conducted to provide evidence on clinical outcomes of interest among patients undergoing open abdominal surgery using STRATAFIX Symmetric for high tension closure. Specifically, this study primarily evaluated the non-inferiority in the cumulative incidence of incisional hernia within 12 months post-index procedure with secondary endpoints of internal wound dehiscence.

Substantial Equivalence Conclusion:
STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices are substantially equivalent to the predicate device.