December 22, 2025

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

Re: K252743
Trade/Device Name: STRATAFIX™ Spiral 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: November 26, 2025
Received: November 26, 2025

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 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
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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)*
K252743

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

Indications for Use *(Describe)*
The STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices are indicated for use in soft tissue approximation where the use of absorbable sutures 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 (K252743)

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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Date Prepared: December 22, 2025

Device Trade Name: STRATAFIX™ Spiral 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™ Spiral PDS™ Plus Bidirectional Knotless Tissue Control Device	K192144	NEW
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	K182873	NEW

Device Description:

STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices are antibacterial monofilament, synthetic absorbable devices consisting of dyed (violet) polyester, poly(p-dioxanone), the empirical molecular formula of which is $(C_4H_6O_3)_x$. The devices contain IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 μg/m. The pigment for the violet dye is D&C Violet No. 2. Polydioxanone polymer has been found to be nonallergenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices are available in Unidirectional and Bidirectional forms:

- The STRATAFIX™ Spiral PDS™ Plus Unidirectional Knotless Tissue Control Devices consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX™ Spiral PDS™ Plus Unidirectional Knotless Tissue Control Device is designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end. Barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.
- The STRATAFIX™ Spiral PDS™ Plus Bidirectional Knotless Tissue Control Device consists of barbed suture material, armed with a surgical needle on each end. The device also contains an un-barbed center transition zone that facilitates the initiation of the device use. The barbs allow for tissue approximation without the need to tie surgical knots.

While the formation of barbs in the STRATAFIX™ Spiral PDS™ Plus Devices reduce the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduces their effective strength. For this reason, the strength of the STRATAFIX™ Spiral PDS™ Plus Devices can be compared to USP knot strength of non-barbed sutures. Additionally, USP designations for diameter are used to describe the STRATAFIX™ Spiral PDS™ Plus Devices suture material after barbing, except for minor variation in suture diameter with a maximum overage of 0.1 mm.

Indications for Use:

The STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices are indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.

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

Comparison of Technological Characteristics with the Predicate Devices:

There are no changes to the technological characteristic of the STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices. The subject devices differ from their respective predicate devices only in the Instructions for Use (IFU). The Instructions for Use of the subject devices are updated with the following change:

Ethicon will remove the warning related to use in gastrojejunal anastomoses for Roux-en-Y gastric bypass in the IFU for STRATAFIX™ Spiral 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 retrospective chart review of hospital electronic medical records was performed to support the update of the STRATAFIX Spiral PDS™ Plus Knotless Tissue Control Devices warning, evaluating robotically-assisted hand-sewn gastrojejunal anastomosis for Roux-en-Y gastric bypass (RYGB) using STRATAFIX Spiral Knotless Tissue Control Devices (KTCD).

A total of 145 patients met the selection criteria for the robotically-assisted hand-sewn gastrojejunal anastomosis cohort. Their demographics are shown in Table 1. There was no inpatient mortality at index and no anastomotic leakage, anastomotic bleeding, bleeding of unspecified origin, or intra-abdominal infection within 30 days post-procedure. There were no cases of reoperations. Three patients (2.1%) experienced anastomotic stricture, which was resolved on follow-up.

Taken together, we believe there is sufficient evidence to justify the removal of the warning statement regarding their use in gastrojejunal anastomoses for Roux-en-y gastric bypass.

Table 1. Demographics of Patient Group Population, n=145

Age category	
18-34	17.20%
34-44	35.20%
45-54	30.30%
55-64	13.10%
65-74	4.10%
75+	0.00%
Female	81.40%
Race	
White	49.70%
Black	42.10%
Other/unknown	8.30%
Ethnicity	
Hispanic	7.60%
Not Hispanic	87.60%
Other/Unknown	4.80%
Diabetes Status	
Diabetes without complications	20.70%
Diabetes with complications	8.30%
Smoking status	
Former smoker	30.30%
Current smoker	0.10%
Body Mass Index Category	
Normal weight: 20 to <25	0.00%
Overweight: 25 to <30	1.40%
Obesity: 30 to <35	6.20%
Obesity: 35.0 to 35.9	2.10%
Obesity: 36.0 to 36.9	2.80%
Obesity: 37.0 to 37.9	2.80%
Obesity: 38.0 to 38.9	5.50%
Obesity: 39.0 to 39.9	3.40%
Obesity: 40.0 to 44.9	28.30%
Obesity: 45.0 to 49.9	20.00%
Obesity: 50.0 to 59.9	21.40%
Obesity: 60.0 to 69.9	5.50%

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