September 24, 2020

Ethicon, Inc.
Joice Pappan
Regulatory Affairs Manager
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K192144
Trade/Device Name: STRATAFIX Spiral PDS Plus Bidirectional Knotless Tissue Control Device

Dear Mr. Joice Pappan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 25, 2020. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
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

March 25, 2020

Ethicon, Inc.
Joice Papan
Regulatory Affairs Manager
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K192144
Trade/Device Name: STRATAFIX Spiral PDS Plus Bidirectional Knotless Tissue Control Device
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: February 21, 2020
Received: February 24, 2020

Dear Mr. Papan:

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,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192144

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

Indications for Use *(Describe)*
STRATAFIX™ Spiral PDS™ Plus Bidirectional Knotless Tissue Control Devices is 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.

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ETHICON, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon, Inc., a *Johnson & Johnson* company
P.O. Box 151
Route 22 West
Somerville, New Jersey 08876-0151
USA

Contact Person: Joice Pappan
Regulatory Affairs Manager
Ethicon, Inc., a *Johnson & Johnson* company
Ph: (908) 218-2113
Fax: (908) 541-3868
Email: Jpappan@its.jnj.com

Date Prepared: March 20, 2020

Device Trade Name: STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device

Device Common Name: Suture, Surgical, Absorbable, Polydioxanone

Class: II

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

Product Code: NEW

Predicate Devices	510(k) Number
STRATAFIX™ Spiral PDS™ *Plus* Knotless Tissue Control Device (Primary)	K182873
Secondary: Quill™ PDO Knotless Tissue Closure Device	K120827

Device Description:

The STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Device is an antibacterial monofilament, synthetic absorbable device consisting of dyed (violet) polyester, poly(p-dioxanone), the empirical molecular formula of which is $(C_4H_6O_3)_X$. The device contains 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* Bidirectional Knotless Tissue Control Device consists of barbed suture material, armed with a surgical needle on each end. The STRATAFIX™ Spiral PDS™ *Plus* Device barbs allow for tissue approximation without the need to tie surgical knots.

While the formation of barbs in the STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Device reduces 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* Bidirectional Device 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* Bidirectional Device suture material after barbing, except for minor variation in suture diameter with a maximum overage of 0.1 mm. The actual diameter of the non-barbed section fiber is one size greater than the designated size with a maximum overage of 0.1 mm.

The USP and EU Pharmacopoeia sizes of the STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Device are further defined in Table 1.

Table 1. Diameter Comparison

USP DEVICE SIZE DESIGNATION	EU PHARMACOPOEIA DEVICE SIZE (Metric / Ph. Eur.) DESIGNATION	STRATAFIX™ Spiral PDS™ *Plus* Bidirectional	
		USP	Metric / Ph. Eur.
1	4	1	4
0	3.5	0	3.5
2-0	3	2-0	3
3-0	2	3-0	2
4-0	1.5	4-0	1.5

Tensile Strength:

STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Device straight tensile strength meets the knot tensile strength for a USP and EU Pharmacopoeia polydioxanone device of the equivalent size as shown in Table 2.

Table 2. Tensile Strength Comparison

USP DEVICE SIZE DESIGNATION	EU PHARMACOPOEIA DEVICE SIZE (Metric / Ph. Eur.) DESIGNATION	Device Minimum Knot Tensile Strength	
		USP (kgf)	Metric / Ph. Eur. (N)
1	4	5.08	50.8
0	3.5	3.90	39.0
2-0	3	2.68	26.8
3-0	2	1.77	17.5
4-0	1.5	0.95	9.32

Indications for Use:

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

Performance Data:

Non-clinical laboratory performance testings were performed to demonstrate that STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device conforms to the current USP Monograph for absorbable surgical sutures, except for diameter. These testings were performed in accordance with FDA's guidance document: "Class II Special Controls Guidance Document: Surgical Sutures – Guidance for Industry and FDA Staff" issued on June 3, 2003. Bench and Animal testings show that the device performed as intended and as claimed.

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Summary of Technological Characteristics and Performance:

The STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device has similar technological characteristics as the predicate devices. Like the currently marketed predicate devices, STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device is a sterile, monofilament synthetic absorbable suture intended for the approximation of soft tissue that conforms to the USP Monograph for absorbable surgical sutures, except for diameter. The STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device consists of barbed suture material, armed with a surgical needle on each end. The barbs in STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Device allow the tissue approximation without the need to tie surgical knots.

STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device will be available as a suture product with IRGACARE ®* MP, an antibacterial agent same as STRATAFIX™ Spiral PDS™ *Plus* Unidirectional predicate device.

Substantial Equivalence:

STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device has the same intended use and indications for use as the predicate devices. The technological differences between the subject device and the predicate devices raise no new questions of safety or effectiveness. STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device meets all criteria to demonstrate substantial equivalence to the predicate devices.

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing, STRATAFIX™ Spiral PDS™ *Plus* Bidirectional Knotless Tissue Control Device has shown to be appropriate for its intended use and is substantially equivalent to the predicate devices.

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