January 10, 2019

Ethicon, Inc.
Dr. Ariell Joiner
Regulatory Affairs Specialist
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K182873
Trade/Device Name: STRATAFIX Symmetric PDS Plus Knotless Tissue Control Devices, STRATAFIX Spiral PDS Plus Knotless Tissue Control Devices, STRATAFIX Spiral MONOCRYL Plus Knotless Tissue Control Devices, STRATAFIX Spiral MONOCRYL Knotless Tissue Control Devices
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW, GAM
Dated: October 11, 2018
Received: October 12, 2018

Dear Dr. Joiner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

K182873

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

Indications for Use *(Describe)*
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.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*

K182873

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

Indications for Use *(Describe)*
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device 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)

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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)*

K182873

Device Name
STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device

Indications for Use *(Describe)*
STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device 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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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)*

K182873

Device Name
STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device

Indications for Use *(Describe)*
STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device 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
a Johnson & Johnson company

510(k) Summary

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

Contact Person: Ariell Joiner
Regulatory Affairs Specialist
Phone: 908-218-2348
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Email: ajoiner@its.jnj.com

Date Prepared: January 07, 2019

Device Trade Name:	STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device and STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device
Device Common Name:	Suture, Surgical, Absorbable Polydioxanone
Class:	II
Classification:	21 CFR 878.4840 – Absorbable Polydioxanone Surgical Suture
Product Code:	NEW
Panel:	General and Plastic Surgery Devices

Device Trade Name:	STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device
Device Common Name:	Suture, Surgical, Absorbable, Polyglycolic Acid
Class:	II
Classification:	21 CFR 878.4493 – Absorbable poly(glycolide/l-lactide) Surgical Suture
Product Code:	GAM
Panel:	General and Plastic Surgery Devices

Predicate Devices:

Device	Product Code	510(k) Number	Predicate for
STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device	NEW	K141776	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	NEW	K150670	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics
STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device	GAM	K151200	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics

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 $(C_4H_6O_3)_x$. 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.

STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control 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 Knotless Tissue Control Device, Variable Loop Design 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 Knotless Tissue Control Device is designed to

anchor with a closed loop at one end and a unidirectional barbed section on the other end. The STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.

While the formation of barbs in the STRATAFIX™ Spiral PDS™ Plus 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 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 Device suture material after barbing, except for minor variation in suture diameter with a maximum overage of 0.1 mm.

STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device is an antibacterial monofilament, synthetic absorbable device prepared from a copolymer of glycolide and ε-caprolactone. The device contains IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360µg/m. Poliglecaprone 25 copolymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device, Variable Loop Design consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX™ Spiral MONOCRYL™ Plus Device is designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end. The STRATAFIX™ Spiral MONOCRYL™ Plus Device barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.

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

STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is a monofilament, synthetic absorbable device prepared from a copolymer of glycolide and ε-caprolactone. Poliglecaprone 25 copolymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device, Variable Loop Design consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX™ Spiral MONOCRYL™ Device is designed to anchor with a closed loop at one end and unidirectional barbed section on the other end. The STRATAFIX™ Spiral MONOCRYL™ Device barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.

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

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

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

The STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.

Summary of Technological Characteristics:

The technological characteristics of the subject devices are identical to their predicate devices, therefore performance data are not necessary to establish substantial equivalence.

The STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device and its predicate device, STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device (K141776), are antibacterial, absorbable, dyed (violet) monofilaments prepared from the polyester, poly (p-dioxanone), with unidirectional anchors, equipped with a surgical needle at one end and a fixation tab at the other to allow for tissue approximation without the need to tie surgical knots.

The STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device and its predicate device, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device (K150670), are both antibacterial, absorbable, dyed (violet) monofilaments prepared from the polyester, poly (p-dioxanone), designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end to allow tissue approximation without the need to tie surgical knots.

The STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device and its predicate device, STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device (K151200), are both antibacterial, absorbable, undyed monofilaments prepared from a copolymer of glycolide and ε-caprolactone, designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end to allow tissue approximation without the need to tie surgical knots.

The STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device and its predicate device, STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device (K151200), are both absorbable, undyed monofilaments prepared from a copolymer of glycolide and ε-caprolactone, designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end to allow tissue approximation without the need to tie surgical knots.

Substantial Equivalence:

The subject devices are identical to their respective predicate devices with respect to functionality, technological characteristics, intended uses, and indications. There are no changes to the material, device construction, performance specifications, packaging, sterilization or manufacturing processes, or shelf life of the currently marketed devices. The subject devices differ from their respective predicate devices only in the labeling (Instructions for Use).

The Instructions for Use of the subject device, STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device, has been revised to add the following three new Warnings to the Warnings Section:

1) Care should be undertaken to avoid leaving barbed suture ends adjacent to the peritoneum in extra-peritoneal tissue closure.
2) Avoid contacting STRATAFIX™ Device and associated needles with other materials (e.g. surgical gauze, drapes, etc.) in the surgical field to prevent ensnaring on the barbs. If the barbs catch, carefully pull the material in the opposite direction of the needle to disengage it from the barbs.
3) Small bowel obstruction (SBO): including volvulus, bowel infarction, and significant morbidity, have been reported due to barbs or barbed suture ends hooking onto adjacent small bowel and/or mesentery, such as in peritoneal closure.

The Instructions for Use of the subject devices, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device, STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device, and STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device have been revised to move one Precaution statement, “Avoid contacting the STRATAFIX™ Device and associated needles with other materials (e.g. surgical gauze, drapes, etc.) in the surgical field to prevent ensnaring on the barbs. If the barbs catch, carefully pull the material in the opposite direction of the needle to disengage it from the barbs” to the Warnings Section and add the following two Warnings to the Warnings Section:

1) Care should be undertaken to avoid leaving barbed suture ends adjacent to the peritoneum in extra-peritoneal tissue closure.
2) Small bowel obstruction (SBO): including volvulus, bowel infarction, and significant morbidity, have been reported due to barbs or barbed suture ends hooking onto adjacent small bowel and/or mesentery, such as in peritoneal closure.

The subject devices do not raise new questions of safety or effectiveness and are therefore substantially equivalent to their respective predicate devices.

Conclusion:

Based on the intended use, fundamental scientific technology and, technological characteristics, the subject devices, STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device, STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device, and STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device are considered to be substantially equivalent to their predicate devices, STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device (K141776), STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device (K150670), and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device and the STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device (K151200), respectively.

[*] *Trademark*
IRGACARE®[*] MP (triclosan) “Registered Trademark of BASF Group”