11/15/2022

Ethicon, Inc.
Jenny Wang
Regulatory Affairs Specialist
1000 Us-202
Raritan, New Jersey 08869-1425

Re: K221744
Trade/Device Name: STRATAFIX™ Spiral MONOCRYL™ Plus Unidirectional Knotless Tissue Control Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: June 15, 2022
Received: June 16, 2022

Dear Jenny Wang:

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,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221744

Device Name

STRATAFIX™ Spiral MONOCRYL™ *Plus* Unidirectional Knotless Tissue Control Device

Indications for Use *(Describe)*

STRATAFIX™ Spiral MONOCRYL™ *Plus* Unidirectional 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, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon Inc. a *Johnson & Johnson* company
1000 US-202
Raritan, New Jersey 08869

Contact Person: Jenny Wang
Ethicon, Inc. a *Johnson & Johnson* company
Phone: 908-440-7850
e-mail: jwang347@its.jnj.com

Date Prepared: November 14, 2022

Device Trade Name: STRATAFIX™ Spiral MONOCRYL™ *Plus* Unidirectional Knotless Tissue Control Device

Device Common Name: Surgical Suture

Class: II

Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid (21 CFR 878.4493)

Product Code: GAM

Predicate Devices	**510(k) Number**	**Purpose**
Primary Predicate Device: STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device	K182873	Predicate for all technological characteristics, Indication for Use, and Performance
Reference Device for Dye: STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device	K192580	Reference device for Dye

Device Description:
The STRATAFIX™ Spiral MONOCRYL™*Plus* Unidirectional Knotless Tissue Control Device is an antibacterial monofilament, synthetic absorbable single-use surgical suture device composed of a copolymer of glycolide and (epsilon) ε-caprolactone. The device contains IRGACARE®‡ MP (triclosan), a broad-spectrum antibacterial agent, at no more than 2360 µg/m. The colorant employed is D&C Violet No.2, in <0.050% w/w concentration. Poliglecaprone 25 copolymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption. The subject device is intended for professional use only.

Same as the currently marketed undyed version, the subject device consists of a unidirectional barbed suture material, armed with a surgical needle on one end and an anchoring fixation loop at the opposite end. The barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.

While the formation of barbs in the subject STRATAFIX™ Spiral MONOCRYL™*Plus* Unidirectional 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 MONOCRYL™ *Plus* Unidirectional Device can be compared to USP knot strength of non-barbed sutures. 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 subject device is sterilized by Ethylene Oxide, and is available in lengths of 6, 9, and 12 inches, with a USP diameter size 2-0 and 3-0 (metric sizes 3.0 and 2.0), and single armed with various needle sizes.

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

Performance Data:
Non-clinical laboratory performance testing on suture loop tensile strength and suture straight tensile strength was performed demonstrating that the subject device conforms to the current USP Monograph for absorbable surgical sutures, except for diameter. The testing was performed in accordance with FDA's Guidance Document: "Class II Special Controls Guidance Document: Surgical Sutures" issued on June 3, 2003. In addition, Suture diameter, Needle Attachment Strength, and In-vivo Breaking Strength Retention (BSR) were evaluated to show that the device performs as intended and as claimed. Stability evaluation was performed to support equivalence to the primary predicate device.

The added colorant in the subject device is the same as that used in the secondary predicate device for dye and does not raise new questions on safety or effectiveness. The subject device meets all testing criteria to demonstrate substantial equivalence to the primary predicate device.

Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use:
The intended use, technological characteristics, and performance of the subject device are consistent with those of the primary predicate device. The subject and primary predicate (K182873) devices are identical except for the addition of the colorant and the subject device is supplied in a subset of sizes. The dye and its concentration used in the subject device is the same as that used in the reference device for dye (K192580), which is comprised of the identical base material but which does not include a welded loop.

The following table summarizes the similarities and differences between the subject device and the predicate and reference devices.

Characteristic	**Subject Device** STRATAFIX™ Spiral MONOCRYL™ *Plus* Unidirectional Device (Dyed)	**Primary Predicate Device** STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device (K182873)	**Reference Device for Dye** STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device (K192580)
Barb Orientation	Unidirectional Barbed suture with a welded loop	Same	Bidirectional Barb suture without a welded loop
Absorbable Suture Material	Copolymer poliglecaprone 25 composed of glycolide and ε-caprolactone	Same	Same
Colorant	D&C Violet No.2 (21CFR §74.3602) in <0.050% w/w concentration	Undyed	Same

Substantial Equivalence:
The subject device has the same intended use and indications for use as the primary predicate device. There is no polymer formulation, construction, specification, body/fluid contact, manufacturing, or sterilization process change to the currently marketed device.

The added colorant in the subject device is the same as that used in the reference device for dye and does not raise new questions on safety or effectiveness.

Conclusion:
Based on the intended use, technological characteristics, and safety and performance testing, and biocompatibility evaluation, the STRATAFIX™ Spiral MONOCRYL™*Plus* Unidirectional Knotless Tissue Control Device has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the primary predicate device.