March 27, 2026

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

Re: K253572
Trade/Device Name: STRATAFIX™ Spiral PRONOVA™ Unidirectional Knotless Tissue Control Device
STRATAFIX™ Spiral PRONOVA™ Bidirectional Knotless Tissue Control Device
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: February 27, 2026
Received: February 27, 2026

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 (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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253572

Device Name
STRATAFIX™ Spiral PRONOVA™ Unidirectional Knotless Tissue Control Device
STRATAFIX™ Spiral PRONOVA™ Bidirectional Knotless Tissue Control Device

Indications for Use *(Describe)*

The STRATAFIX™ Spiral PRONOVA™ Unidirectional Device is indicated for use in soft tissue approximation where the use of a non-absorbable barbed suture is appropriate, excluding closure of the epidermis.

The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device is indicated for use in soft tissue approximation where the use of a non-absorbable barbed suture is appropriate, excluding closure of the epidermis.

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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510(k) Summary
(K253572)

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

Contact Person: Jenny Wang
Ethicon, Inc. a *Johnson & Johnson* company
e-mail: jwang347@its.jnj.com
Phone: (646)896-9786

Date Prepared: December 17, 2025

Device Trade Name: STRATAFIX™ Spiral PRONOVA™ Unidirectional Knotless Tissue Control Device
STRATAFIX™ Spiral PRONOVA™ Bidirectional Knotless Tissue Control Device

Device Common Name: Nonabsorbable polypropylene surgical suture

Class: II

Classification Name: Suture, Nonabsorbable, Synthetic, Polypropylene
(21 CFR 878.5010)

Product Code: GAW

Legally Marketed Predicate Devices	**510(k) Number**	**Product Code**
Primary Predicate Device:		
QUILL™ NONABSORBABLE POLYPROPYLENE BARBED SUTURE (Bidirectional)	K052373	GAW
Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design (Unidirectional)	K151112	GAW
Reference Predicate Devices (for Material):		
PRONOVA™ NONABSORBABLE SUTURE, USP	K001625	GAW

* The predicate devices have not been subject to a design-related recall.

Device Description:

The STRATAFIX™ Spiral PRONOVA™ Knotless Tissue Control Devices (KTCD) are monofilament, synthetic non-absorbable devices composed of a polymer blend of poly (vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene). The STRATAFIX™ Spiral PRONOVA™ KTCD are pigmented blue to enhance visibility in the surgical field. The STRATAFIX™ Spiral PRONOVA™ KTCD has two variations based on the orientation of the barbs and needle attachment: STRATAFIX™ Spiral PRONOVA™ Unidirectional KTCD and STRATAFIX™ Spiral PRONOVA™ Bidirectional KTCD.

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

The STRATAFIX™ Spiral PRONOVA™ Bidirectional KTCD Design consists of barbed suture material, armed with a surgical needle on each end. The device also contains an unbarbed center transition zone that facilitates the initiation of the device use. The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device barbs allow for tissue approximation without the need to tie surgical knots.

The subject devices are for single-use and are sterilized by Ethylene Oxide. The subject devices are available in various lengths and USP diameter sizes armed with various needle sizes. STRATAFIX™ Spiral PRONOVA™ KTCD is intended for use only by Healthcare Professionals who are trained in surgical suturing techniques.

Indications for Use:

The STRATAFIX™ Spiral PRONOVA™ Unidirectional Device is indicated for use in soft tissue approximation where the use of a non-absorbable barbed suture is appropriate, excluding closure of the epidermis.

The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device is indicated for use in soft tissue approximation where the use of a non-absorbable barbed suture is appropriate, excluding closure of the epidermis.

The subject devices and the primary predicate devices are all indicated for soft tissue approximation.

Comparison of Technological Characteristics with the Predicate Devices:

Substantial Equivalence Comparison Table:

Technological Characteristic	**Subject Devices:** STRATAFIX™ Spiral PRONOVA™ Unidirectional KTCD	**Primary Predicate Devices:** QUILL™ Polypropylene Knotless Tissue Closure Device, Variable Loop Design (Unidirectional) K151112	**Reference Predicate Device for Material:** PRONOVA™ NONABSORBABLE SUTURE, USP (K001625)	**Conclusion**
	STRATAFIX™ Spiral PRONOVA™ Bidirectional KTCD	QUILL™ NONABSORBABLE POLYPROPYLENE BARBED SUTURE (Bidirectional) K052373		
Indications for Use	The STRATAFIX™ Spiral PRONOVA™ Unidirectional Device is indicated for use in soft tissue approximation where the use of a non-absorbable barbed suture is appropriate, excluding closure of the epidermis.	Quill Unidirectional: Quill™ Knotless Tissue-Closure Device comprised of Polypropylene is indicated for soft tissue approximation, excluding closure of the epidermis.	PRONOVA™ Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and neurological procedures.	**EQUIVALENT**
	The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device is indicated for use in soft tissue approximation where the use of a non-absorbable barbed suture is appropriate, excluding closure of the epidermis.	Quill Bidirectional: Quill™ Nonabsorbable Polypropylene Barbed Sutures are indicated for use in soft tissue approximation, excluding closure of the epidermis.		
Contraindications	The STRATAFIX™ Spiral PRONOVA™ Unidirectional Device is not indicated for surface closures through the epidermis as the barbs make the STRATAFIX™ Spiral PRONOVA™ Unidirectional Device removal unfeasible.	Quill Unidirectional and Bidirectional: Quill™ Barbed Suture comprised of polypropylene is not indicated for surface closures through the epidermis as the small opposing facing barbs make Quill ™ Barbed Suture removal unfeasible.	None known.	**EQUIVALENT**
	The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device is not indicated for surface closures through the epidermis as the small opposing facing barbs make the			

Technological Characteristic	Subject Devices: STRATAFIX™ Spiral PRONOVA™ Unidirectional KTCD	Primary Predicate Devices: QUILL™ Polypropylene Knotless Tissue Closure Device, Variable Loop Design (Unidirectional) K151112	Reference Predicate Device for Material: PRONOVA™ NONABSORBABLE SUTURE, USP (K001625)	Conclusion
	STRATAFIX™ Spiral PRONOVA™ Bidirectional KTCD	QUILL™ NONABSORBABLE POLYPROPYLENE BARBED SUTURE (Bidirectional) K052373		
	STRATAFIX™ Spiral PRONOVA™ Bidirectional Device removal unfeasible.			
Technological Means for Achieving Intended Use	Mechanically barbed monofilament strand to approximate tissue anchored without the need to tie surgical knots.	Mechanically barbed monofilament strand to approximate tissue anchored without the need to tie surgical knots.	Monofilament strand to approximate tissue anchored with surgical Knots.	**EQUIVALENT**
Suture Design	The STRATAFIX™ Spiral PRONOVA™ Unidirectional Device: Monofilament synthetic suture Single armed Unidirectional barbs made by cutting into the core of the suture strand Contains a welded primary loop and secondary loop	Quill Unidirectional: Monofilament synthetic suture Single armed Unidirectional barbs made by cutting into the core of the suture strand Contains a welded primary loop and secondary loop	Monofilament synthetic suture strand Single armed	**EQUIVALENT**
	The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device: Monofilament synthetic suture Double armed Opposite facing barbs from the non-barbed center transition zone	Quill Bidirectional: Monofilament synthetic suture Double armed Opposite facing barbs from the non-barbed center transition zone		
Suture Material	Sterile, monofilament, synthetic non-absorbable device composed of a polymer blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).	The Quill'" Barbed Suture is comprised of an isotactic polypropylene polymer of high molecular weight.	Sterile, monofilament, synthetic, non-absorbable surgical suture composed of a polymer blend of poly (vinylidene fluoride) and	**EQUIVALENT**

Technological Characteristic	Subject Devices: STRATAFIX™ Spiral PRONOVA™ Unidirectional KTCD	Primary Predicate Devices: QUILL™ Polypropylene Knotless Tissue Closure Device, Variable Loop Design (Unidirectional) K151112	Reference Predicate Device for Material: PRONOVA™ NONABSORBABLE SUTURE, USP (K001625)	Conclusion
	STRATAFIX™ Spiral PRONOVA™ Bidirectional KTCD	QUILL™ NONABSORBABLE POLYPROPYLENE BARBED SUTURE (Bidirectional) K052373		
			poly (vinylidene fluoride-co-hexafluoropropylene).	
Suture Colorant	Pigmented blue with phthalocyanine blue (Color Index Number 74160) to enhance visibility	The pigment for the blue dyed suture material is Phthalocyaninato (2-) Copper	Pigmented blue with phthalocyanine blue (Color Index Number 74160) to enhance visibility	**EQUIVALENT**
USP Suture Size	The STRATAFIX™ Spiral PRONOVA™ Unidirectional Device: 0, 2-0, and 3-0	Quill Unidirectional: 2-0 through 2	Sizes 10-0 through 8-0 and 6-0 through 2	**EQUIVALENT**
	The STRATAFIX™ Spiral PRONOVA™ Bidirectional Device: 0 and 2-0	Quill Bidirectional: 3-0 through 2		
Suture Diameter	The suture diameters comply with diameter requirements listed in USP <861> Diameter.	The suture diameters comply with diameter requirements listed in USP <861> Diameter.	The suture diameters comply with diameter requirements listed in USP <861> Diameter.	**EQUIVALENT**
Tensile Strength	Straight Tensile meets USP <881> Knot Tensile requirements for Synthetic Non-absorbable Sutures of the same size equivalent	Strength of the Quill™ Barbed Suture can be compared to USP <881> Knot Tensile Strength of non-barbed sutures	Tensile strength complies with the tensile requirement listed in USP <881> Knot Tensile Strength.	**EQUIVALENT**
Needle Pull-Off	Meets USP <871> requirements	Meets USP <871> requirements	Meets USP <871>requirements	**EQUIVALENT**
Absorption Profile	Nonabsorbable	Nonabsorbable	Nonabsorbable	**EQUIVALENT**

Technological Characteristic	**Subject Devices:** STRATAFIX™ Spiral PRONOVA™ Unidirectional KTCD	**Primary Predicate Devices:** QUILL™ Polypropylene Knotless Tissue Closure Device, Variable Loop Design (Unidirectional) K151112	**Reference Predicate Device for Material:** PRONOVA™ NONABSORBABLE SUTURE, USP (K001625)	**Conclusion**
	STRATAFIX™ Spiral PRONOVA™ Bidirectional KTCD	QUILL™ NONABSORBABLE POLYPROPYLENE BARBED SUTURE (Bidirectional) K052373		
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	**EQUIVALENT**
Single Use?	Yes	Yes	Yes	**EQUIVALENT**
FDA Regulation	21 CFR 878.5010: Nonabsorbable polypropylene surgical suture	21 CFR 878.5010: Nonabsorbable polypropylene surgical suture	21 CFR 878.5010: Nonabsorbable polypropylene surgical suture	**EQUIVALENT**
FDA Product Code	GAW	GAW	GAW	**EQUIVALENT**

FDA's Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28, 2014 was followed and it was concluded that based on the intended use, technological characteristics, and safety and performance testing, the subject devices have been shown to be appropriate for its intended use and are considered to be substantially equivalent to the legally marketed predicate devices as demonstrated in the above Substantial Equivalence Comparison table.

The slight technological differences between the subject devices and the predicate devices do not raise new questions of safety or effectiveness. The subject device met all testing criteria to demonstrate substantial equivalence to the predicate devices.

Performance Data:

Mechanical bench-top testing, animal testing, and biocompatibility testing collectively demonstrated that the subject devices performed as intended and as claimed and are substantially equivalent to the predicate devices.

Non-clinical laboratory performance testing was performed demonstrating that the subject device conforms to the current USP Monograph for non-absorbable surgical sutures, including <861> suture diameter, <871> suture attachment, and <881>tensile strength. The testing was performed in accordance with FDA's Guidance Document: "Class II Special Controls Guidance Document: Surgical Sutures" issued on June 3, 2003.

Additionally, Wound Holding related testing was conducted and the results demonstrate the substantial equivalence of STRATAFIX™ Spiral PRONOVA™ Unidirectional and Bidirectional Knotless Tissue Control Devices (KTCD) compared to the Primary Predicate Devices.

The biocompatibility evaluation for the subject devices was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA.

Furthermore, GLP compliant pre-clinical animal study was performed to evaluate wound healing. The study outcomes demonstrated substantial equivalence of the subject devices, STRATAFIX™ Spiral PRONOVA™ Unidirectional and Bidirectional Knotless Tissue Control Devices, to the performances of the Primary and Reference Predicate Devices.

This submission does not include Clinical Study data.

Conclusion:

STRATAFIX™ Spiral PRONOVA™ Unidirectional and Bidirectional Knotless Tissue Control Devices are substantially equivalent to the predicate devices.