April 25, 2024

M/s. Meril Endo Surgery Private Limited
Asma Shaikh
Assistant Manager- Regulatory Affairs
Third Floor, E1-E3, Meril Park Survey
No. 135/2/B & 174/2, Muktanand Marg, Chala
Vapi, Gujarat 396191
India

Re: K232246
Trade/Device Name: 1) PINION™ PDO Knotless Suture - Absorbable Poly (P-Dioxanone) Knotless Suture; 2) PINION™ PGA-PCL Knotless Suture - Absorbable Polyglycolic Acid - Poly (Glycolide-Co-Caprolactone) Knotless Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW, GAM
Dated: July 28, 2023
Received: March 25, 2024

Dear Asma Shaikh:

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.

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

Digitally signed by Tek N. Lamichhane -S
Date: 2024.04.25 15:43:22 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232246

Device Name

1) PINION™ PDO Knotless Suture - Absorbable Poly (P-Dioxanone) Knotless Suture;
2) PINION™ PGA-PCL Knotless Suture - Absorbable Poly (Glycolide-Co-Caprolactone) Knotless Suture

Indications for Use *(Describe)*

1. PINION™ PDO Knotless Sutures are indicated for use in general soft tissue approximation where use of an absorbable suture is appropriate.

2. PINION™ PGA-PCL Knotless Sutures are indicated for use in 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.

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510(K) SUMMARY
K232246

I. *SUBMITTER*

M/s. Meril Endo Surgery Private Limited.

Third Floor, E1 – E3, Meril Park,

Survey No. 135/2/B & 174/2, Muktanand Marg,

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Applicant Information

Mr. Umesh Sharma

General Manager – Quality Assurance / Regulatory Affairs

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Primary Correspondent Information

Asma Shaikh

Assistant Manager – Regulatory Affairs

E-mail: asma.shaikh@merillife.com

Date Prepared: April 24th, 2024

II. *SUBJECT DEVICE*

Trade / Proprietary Name	PINION™ PDO Knotless Suture
Common Name	Suture, Surgical, Absorbable Polydioxanone
Classification	Absorbable Polydioxanone Surgical Suture
Regulatory Class	II
Product Code	NEW
Regulation Number	21 CFR 878.4840
Review Panel	General & Plastic Surgery Devices Panel

510(K) SUMMARY
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Trade / Proprietary Name	PINION™ PGA-PCL Knotless Suture
Common Name	Suture, Surgical, Absorbable Polyglycolic Acid
Classification	Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class	II
Product Code	GAM
Regulation Number	21 CFR 878.4493
Review Panel	General & Plastic Surgery Devices Panel

III. *PREDICATE DEVICE*

Subject device (K232246)	**Predicate device**		
	Trade Name	**Manufacturer**	**510 (K) No.**
PINION™ PDO Knotless Suture	STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device	Ethicon Inc.	K182873
PINION™ PGA-PCL Knotless Suture	STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device*(Primary Predicate)*	Ethicon Inc.	K151200
	STRATAFIX™ Spiral MONOCRYL™ Plus Unidirectional Knotless Tissue Control Device		K221744

IV. *Device Description*

PINION™ PDO KNOTLESS SUTURE

The **PINION™ PDO Knotless Suture** consists of barbed suture material armed with a surgical needle on each end. Barbs allow for tissue approximation without the need to tie surgical knots.

PINION™ PDO Knotless Suture is a sterile, synthetic, absorbable monofilament suture comprised of Poly (p- Polydioxanone). The empirical molecular formula of which is $(C_4H_6O_3)_x$. PINION™ PDO Knotless Sutures are available in undyed or dyed with D & C violet No.2 (21 CFR 74. 3602) at a level not exceeding 0.3 % by weight of the suture in sizes USP (EP) 3-0 (2), 2-0 (3) & 0 (3.5). It is supplied with the attached stainless steel surgical needles. Polydioxanone has been found to be nonantigenic, nonpyrogenic and to elicit only a slight tissue reaction during absorption.

The PINION™ PDO Knotless Suture is designed with small unidirectional and bidirectional barbs along the length of the device. It consists of an absorbable thread with unidirectional anchors, equipped with a

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surgical needle at one end and a fixation tab at the other while the bidirectional anchors equipped with a surgical needle at both end. The anchors and fixation tab design allows for tissue approximation without the need to tie surgical knots.

The USP designations for diameter are applicable to the PINION™ PDO Knotless Suture material prior to barbing. After the creation of barbs, the PINION™ PDO Knotless Suture is identified as one size smaller than the non-barbed suture. This modification reduces the tensile strength of the suture similar to effect of knot tying in non-barbed suture. Therefore, the straight pull tensile strength of the PINION™ PDO Knotless Suture is comparable to the USP knot pull tensile strength for a non barbed suture of the equivalent size. The non-barbed size and equivalent size of the PINION™ PDO Knotless Suture is further clarified in Table 1.
The maximum oversize for non barbed suture material from the USP Size is further detailed in Table 2.

The PINION™ PDO Knotless Suture meets requirements established by the United States Pharmacopoeia (USP) for Synthetic absorbable sutures for needle attachments only.

Tensile Strength/Size Equivalency Table 1

PINION™ PDO Knotless Suture	Pre-Barbing Suture Size	Equivalent Non-barbed Suture Size (USP)/Tensile Strength (kgf)
3-0	2-0	3-0/1.77
2-0	0	2-0/2.68
0	1	0/3.90

Maximum Oversize for non-barbed suture material in diameter (mm) from USP Table 2

PINION™ PDO Knotless Suture	USP Size Designations (mm)	PINION™ PDO Knotless Suture Diameter Specification (mm)
3-0	0.200-0.249	0.300-0.349
2-0	0.300-0.349	0.350-0.399
0	0.350-0.399	0.400-0.499

The PINION™ PDO Knotless Suture is MR Safe.

PINION™ PGA-PCL KNOTLESS SUTURE

The **PINION™ PGA-PCL Knotless Suture** consists of barbed suture material armed with a surgical needle on each end. Barbs allow for tissue approximation without the need to tie surgical knots.
PINION™ PGA-PCL Knotless Suture is a sterile, synthetic, absorbable monofilament suture comprised of poly (glycolide-co-caprolactone).

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PINION™ PGA-PCL Knotless Suture is provided undyed or dyed with D & C violet No.2 (21 CFR 74. 3602) at a level not exceeding 0.25 % by weight of the suture in sizes USP (EP) 4-0 (1.5), 3-0 (2) & 2-0 (3). It is supplied with the attached stainless steel surgical needles. The polymer has been found to be nonantigenic, nonpyrogenic and eliciting only a slight tissue reaction during absorption.

The PINION™ PGA-PCL Knotless Suture is designed with small unidirectional and bidirectional barbs along the length of the device. It consists of an absorbable thread with unidirectional anchors, equipped with a surgical needle at one end and a fixation tab at the other while the bidirectional anchors equipped with a surgical needle at both end. The anchors and fixation tab design allows for tissue approximation without the need to tie surgical knots.

The USP designations for diameter are applicable to the PINION™ PGA-PCL Knotless Suture material prior to barbing. After the creation of barbs, the PINION™ PGA-PCL Knotless Suture is identified as one size smaller than the non-barbed suture. This modification reduces the tensile strength of the suture similar to effect of knot tying in non-barbed suture. Therefore, the straight pull tensile strength of the PINION™ PGA-PCL Knotless Suture is comparable to the USP knot pull tensile strength for a non barbed suture of the equivalent size. The non-barbed size and equivalent size of the PINION™ PGA-PCL Knotless Suture is further clarified in Table 1.
The maximum oversize for non barbed suture material from the USP Size is further detailed in Table 2.

The PINION™ PGA-PCL Knotless Suture meets requirements established by the United States Pharmacopoeia (USP) for Synthetic absorbable sutures for needle attachments only.

Tensile Strength/Size Equivalency Table 1

PINION™ PGA-PCL Knotless Suture	Pre-Barbing Suture Size	Equivalent Non-barbed Suture Size (USP)/Tensile Strength (kgf)
4-0	3-0	4-0/0.95
3-0	2-0	3-0/1.77
2-0	0	2-0/2.68

Maximum Oversize for non-barbed suture material in diameter (mm) from USP Table 2

PINION™ PGA-PCL Knotless Suture	USP Size Designations (mm)	PINION™ PGA-PCL Knotless Suture Diameter Range (mm)
4-0	0.150-0.199	0.200-0.249
3-0	0.200-0.249	0.300-0.349
2-0	0.300-0.349	0.350-0.399

The PINION™ PGA-PCL Knotless Suture is MR Safe.

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V. *Indications for Use*

PINION™ PDO Knotless Sutures are indicated for use in general soft tissue approximation where use of an absorbable suture is appropriate.

PINION™ PGA-PCL Knotless Sutures are indicated for use in general soft tissue approximation where use of an absorbable suture is appropriate.

VI. *Comparison of Technological Characteristics with the predicate device*

The PINION™ PDO & PINION™ PGA-PCL Knotless Sutures are substantially equivalent to marketed predicate device with respect to intended use and physical characteristics. The PINION™ PDO & PINION™ PGA-PCL Knotless Sutures have same material, mechanism of action, performance and packaging as predicate devices.

The following characteristics were compared between the subject device and the predicate device in order to demonstrate the substantial equivalence.

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The below table provides the comparison of key features of the subject device and predicate devices.

Table 1: PINION™ PDO Knotless Suture

Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
1.	Device Name	PINION™ PDO Knotless Suture	STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device	-
2.	Manufacturer	Meril EndoSurgery Pvt. Ltd.	Ethicon Inc.	-
3.	510(K) Number	K232246	K182873	-
4.	Common Name	Absorbable Polydioxanone surgical suture	Absorbable Polydioxanone surgical suture	No change
5.	Class	II	II	No change
6.	Product Code	NEW	NEW	No change
7.	Regulation Number	CFR 878.4840	CFR 878.4840	No change
8.	Intended use	**PINION™ PDO Knotless Suture** is indicated for use in general soft tissue approximation where use of an absorbable suture use is appropriate.	STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.	Identical
9.	For single use only	Single use only	Single use only	No change
10	Mode of Actions	Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). PINION™ PDO Knotless Suture has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound healing period and	Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound	Identical

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
		an extended healing period. The results of in vitro study using PINION™ PDO Knotless Suture indicate that approximately 70-80% of the original strength remains after two weeks and four weeks of study. At six weeks approximately 40-50% of the original strength is retained. The absorption of PINION™ PDO Knotless Suture is minimal until about 120 days and complete absorption usually takes place within 180 days (six months).	healing period and an extended healing period. The results of implantation studies in animals using STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices indicates that for sizes 3-0 and larger, approximately 80 % of the original strength remains after two weeks and four weeks of implantation. At six weeks post implantation, approximately 40% to 70% of the original strength is retained. For Size 4-0, approximately 67 % of the original tensile strength remains after two weeks, approximately 50% at 4 weeks, and approximately 37 % at 6 weeks. Data obtained from implantation studies show that absorption of STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Devices is minimal until about 120 days and is essentially complete within 180 days (six months).	
11	Material composition	poly (p-dioxanone)	poly (p-dioxanone)	No change
12	Body Contact	Tissue/Bone/Blood	Tissue/Bone/Blood	No change
13	Shelf Life	5 Year	5 Year	No change
14	Size availability	3-0 to 0	3-0 to 1	Identical; Suture size is covered by the Predicate Suture Range
15	Absorbable/Non Absorbable	Absorbable	Absorbable	No change
16	Braided/	Monofilament	Monofilament	No change

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Sr. No.	Characteristics	Subject Device		Predicate Device	Safety / Effectiveness
	Monofilament				
17	Dyed / Undyed	Undyed or Dyed Suture Strands		Undyed or Dyed Suture Strands	No change
18	Colorant	D&C Violet No. 2		D&C Violet No. 2	No change
19	Coated / Uncoated	Uncoated		Uncoated	No change
20	Types of Barbs	Uni-directional, Bi-directional		Uni-directional, Bi-directional	No change
21	No. of barbs per linear length of Suture	13-17 barbs per cm		10 barbs per cm	No. of Barbs is more in subject device than predicate device which provides more safety to device.
22	Barb Angle	3-0	35-45 **(∠˚)**	23 -28 **(∠˚)**	Different; While there are difference in cut angle between the subject device and the predicate device, these do not raise the new questions of safety and effectiveness as the average barb holding strength for the subject is equivalent to that of the predicate device.
		2-0	40-50 **(∠˚)**		
		0	35-45 **(∠˚)**		
23	Barb Height	3-0	0.250-0.350 mm	0.400 – 0.550 mm	Different; While there are difference in Barb Length between the subject device and the predicate device, these do not raise the new questions of safety and effectiveness as the average barb holding strength for the subject is equivalent to that of the predicate device.
		2-0	0.300-0.400 mm		
		0	0.350-0.450 mm		
24	Barb Shape	Cog Shape		Cog Shape	No change
25	Barb Direction (Bidirectional)	A section and B section in opposite direction.		A section and B section in opposite direction.	No change
26	Barb Direction (Unidirectional)	A section and B section in same direction.		A section and B section in same direction.	No change

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
27	Complete Absorption	within 180 to 210 days	within 180 to 210 days	No change
28	Sterilization method	Ethylene Oxide	Ethylene Oxide	No change
29	Needle Material	Stainless Steel	Stainless Steel	No change
30	Packaging	***Primary Packaging*** – Suture is wound on plastic tray and further packed in Aluminium Foil and Sealed in Tyvek lid. ***Secondary Packaging*** – Primary packed suture are placed in Dispenser Box.	***Primary Packaging*** – Suture is wound on plastic tray and further packed in Aluminium Foil and Sealed in Tyvek lid. ***Secondary Packaging*** – Primary packed suture are placed in Dispenser Box.	Identical
31	Label Claim	Complies with the requirements of the United States Pharmacopoeia for "Synthetic Absorbable Surgical Suture" (except for diameter)	Complies with the requirements of the United States Pharmacopoeia for "Synthetic Absorbable Surgical Suture" (except for diameter)	No change
32	Diameter USP <861>	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Diameter<861>, except for diameter for some oversize suture.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Diameter<861>, except for diameter for some oversize suture.	Identical
	Tensile strength USP <88I>	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Tensile strength <881>.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Tensile strength <881>. Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures for same suture size equivalent.	No change

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
	Needle attachment USP <871>	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Needle attachment <871>.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Needle attachment <871>.	No change
33	Labeling and Instructions for use (IFU).	Labeling conforming to 21CFR 801.109 and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions.	Labeling conforming to 21CFR 801.109 and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions	No change
34	Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	No change

The **PINION™ PGA-PCL Knotless Sutures** are substantially equivalent with the predicate devices contained in the following Table 2.

Table 2: PINION™ PGA-PCL Knotless Suture

Sr. No.	Characteristics	Subject Device	Predicate Device *(Primary Predicate)*	Predicate Device	Safety / Effectiveness
1.	Device Name	PINION™ PGA PCL Knotless Suture	STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device	STRATAFIX™ Spiral MONOCRYL™ Plus Unidirectional Knotless Tissue Control Device	-
2.	Manufacturer	Meril EndoSurgery Pvt. Ltd.	Ethicon Inc.	Ethicon Inc.	-
3.	510(K) Number	K232246	K151200	K221744	-
4.	Common Name	Absorbable poly(glycolide/l-lactide) surgical suture	Absorbable poly(glycolide/l-lactide) surgical suture	Absorbable poly(glycolide/l-lactide) surgical suture	No change
5.	Class	II	II	II	No change
6.	Product Code	GAM	GAM	GAM	No change
7.	Regulation	21 CFR 878.4493	21 CFR 878.4493	21 CFR 878.4493	No change

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<table>
<tr><th>Sr. No.</th><th>Characteristics</th><th>Subject Device</th><th>Predicate Device (Primary Predicate)</th><th>Predicate Device</th><th>Safety / Effectiveness</th></tr>
<tr><td></td><td>Number</td><td></td><td></td><td></td><td></td></tr>
<tr><td>8.</td><td>Intended use</td><td>PINION™ PGA PCL Knotless Suture is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate.</td><td>STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Devices are indicated for use in soft tissue approximation where the use of absorbable suture is appropriate.</td><td>STRATAFIX™ Spiral MONOCRYL™ Plus Unidirectional Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate.</td><td>Identical</td></tr>
<tr><td>9.</td><td>For single use only</td><td>Single use only</td><td>Single use only</td><td>Single use only</td><td>No change</td></tr>
<tr><td>10.</td><td>Mode of Actions</td><td>Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). PINION™ PDO Knotless Suture has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound healing period and an extended healing period.

PINION™ PGA-PCL Knotless Suture retains approximately 62 % of its original strength 7 days post implantation and approximately 46 %</td><td>Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound healing period and an extended healing period.

The results of implantation studies in animals using STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device indicate that approximately 62% of its original strength remains after 7 days implantation and approximately 27% of its original tensile strength at 14 days post implantation. All of the original tensile strength is lost</td><td>Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). STRATAFIX™ Spiral MONOCRYL™ Plus Unidirectional Knotless Tissue Control Device has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound healing period and an extended healing period.

The results of implantation studies in animals using STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue
Table 3. In Vivo Tensile Strength Profile
<table><tr><th>DAYS IMPLANTATION</th><th>APPROXIMATE % ORIGINAL STRENGTH REMAINING</th></tr><tr><td>7 Days</td><td>62 % of USP</td></tr></table></td><td>Identical</td></tr>
</table>

510(K) SUMMARY

K232246

<table>
<tr><th>Sr. No.</th><th>Characteristics</th><th>Subject Device</th><th>Predicate Device (Primary Predicate)</th><th>Predicate Device</th><th>Safety / Effectiveness</th></tr>
<tr><td></td><td></td><td>of its original tensile strength at 14 days post implantation all of the original tensile strength is lost by 28 days post implantation.

The absorption of PINION™ PGA-PCL Knotless Suture is essentially completed between 90 and 120 days.</td><td>by 21 days post implantation. The absolute strength remaining 14 days post implantation meets or exceeds that historically observed with plain or chromic surgical gut devices (Table 3).

Table 3. In Vivo Tensile Strength Profile<table><tr><th>DAYS IMPLANTATION</th><th>APPROXIMATE % ORIGINAL STRENGTH REMAINING</th></tr><tr><td>7 Days</td><td>62 % of USP Knot Tensile Strength</td></tr><tr><td>14 Days</td><td>27 % of USP Knot Tensile Strength</td></tr></table>Data obtained from implantation studies show that absorption of STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Device is essentially complete by 91 days.</td><td><table><tr><td></td><td>Knot Tensile Strength</td></tr><tr><td>14 Days</td><td>27 % of USP Knot Tensile Strength</td></tr></table>Data obtained from implantation studies show that absorption of STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Device is essentially complete by 91 days.</td><td></td></tr>
<tr><td>11.</td><td>Material composition</td><td>Copolymer of (glycolide and ε carprolactone)(PGA-PCL)</td><td>Copolymer of (glycolide and ε carprolactone)(PGA-PCL)</td><td>Copolymer of (glycolide and ε carprolactone)(PGA-PCL)</td><td>No change</td></tr>
<tr><td>12.</td><td>Body Contact</td><td>Tissue/Bone/Blood</td><td>Tissue/Bone/Blood</td><td>Tissue/Bone/Blood</td><td>No change</td></tr>
<tr><td>13.</td><td>Shelf Life</td><td>5 Year</td><td>5 Year</td><td>5 Year</td><td>No change</td></tr>
<tr><td>14.</td><td>Size availability</td><td>4-0 to 2-0</td><td>4-0 to 2-0</td><td>4-0 to 2-0</td><td>No change</td></tr>
<tr><td>15.</td><td>Absorbable/Non</td><td>Absorbable</td><td>Absorbable</td><td>Absorbable</td><td>No change</td></tr>
</table>

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Sr. No.	Characteristics	Subject Device		Predicate Device *(Primary Predicate)*	Predicate Device	Safety / Effectiveness
	Absorbable					
16.	Braided/ Monofilament	Monofilament		Monofilament	Monofilament	No change
17.	Dyed / Undyed	Undyed or Dyed Suture Strands		Undyed or Dyed Suture Strands	Undyed or Dyed Suture Strands	No change
18.	Colorant (if Dyed)	D&C Violet No. 2		D&C Violet No. 2	D&C Violet No. 2	No change
19.	Coated / Uncoated	Uncoated		Uncoated	Uncoated	No change
20.	Types of Barbs	Uni-directional, Bi-directional		Bi-directional	Uni-directional	Both types are covered by predicate device
21.	No. of barbs per linear length of Suture	17-22 barbs per cm		10 barbs per cm	10 barbs per cm	No. of Barbs is more in subject device than predicate device which provides more safety to device.
22.	Barb Angle	4-0	58-63 **(∠˚)**	23 -38 **(∠˚)**	Not Known	Different; While there are difference in cut angle between the subject device and the predicate device, these do not raise the new questions of safety and effectiveness as the average barb holding strength for the subject is equivalent to that of the predicate device.
		3-0	35-45 **(∠˚)**			
		2-0	40-50 **(∠˚)**			

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Sr. No.	Characteristics	Subject Device		Predicate Device *(Primary Predicate)*	Predicate Device	Safety / Effectiveness
23.	Barb Height	4-0	0.253-0.283 mm	0.350 – 0.550 mm	Not Known	Different; While there are difference in barb length between the subject device and the predicate device, these do not raise the new questions of safety and effectiveness as the average barb holding strength for the subject is equivalent to that of the predicate device.
		3-0	0.250-0.350 mm			
		2-0	0.300-0.400 mm			
24.	Barb Shape	Cog Shape		Cog Shape	Cog Shape	No change
25.	Barb Direction (Bidirectional)	A section and B section in opposite direction.		A section and B section in opposite direction.	NA	No change
26.	Barb Direction (Unidirectional)	A section and B section in same direction.		NA	A section and B section in same direction.	No change
27.	Absorption Profile	between 90 and 120 days.		essentially complete by 91 days.	essentially complete by 91 days.	Identical
28.	Sterilization method	Ethylene Oxide		Ethylene Oxide	Ethylene Oxide	Identical
29.	Needle Material	Stainless Steel		Stainless Steel	Stainless Steel	Identical
30.	Packaging Configuration	***Primary Packaging*** – Suture is wound on plastic tray and further packed in Aluminium Foil and Sealed in Tyvek lid. ***Secondary Packaging*** –		***Primary Packaging*** – Suture is wound on plastic tray and further packed in Aluminium Foil and Sealed in Tyvek lid. ***Secondary Packaging*** – Primary packed suture are placed in Dispenser Box.	***Primary Packaging*** – Suture is wound on plastic tray and further packed in Aluminium Foil and Sealed in Tyvek lid. ***Secondary Packaging*** – Primary packed suture are placed in Dispenser Box.	Identical

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Sr. No.	Characteristics	Subject Device	Predicate Device *(Primary Predicate)*	Predicate Device	Safety / Effectiveness
		Primary packed suture are placed in Dispenser Box.			
31.	Label Claim	Complies with the requirements of the United States Pharmacopoeia for "Synthetic Absorbable Surgical Suture" (except for diameter)	Complies with the requirements of the United States Pharmacopoeia for "Synthetic Absorbable Surgical Suture" (except for diameter)	Complies with the requirements of the United States Pharmacopoeia for "Synthetic Absorbable Surgical Suture" (except for diameter)	Identical
32.	**Performance**				
	Diameter USP <861>	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Diameter<861>, except for diameter for some oversize suture.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Diameter<861>, except for diameter for some oversize suture.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Diameter<861>, except for diameter for some oversize suture.	No change
	Tensile strength USP <88I>	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Tensile strength <881>.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Tensile strength <881>. Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures for same suture size equivalent.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Tensile strength <881>. Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures for same suture size equivalent.	No change
	Needle attachment USP <871>	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Needle attachment <871>.	Finished suture material meets the performance requirements defined in the United States Pharmacopeia for Needle attachment <871>.	No change

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Sr. No.	Characteristics	Subject Device	Predicate Device *(Primary Predicate)*	Predicate Device	Safety / Effectiveness
		Needle attachment <871>.			
33.	Labeling and Instructions for use (IFU).	Labeling conforming to 21CFR 801.109 and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions.	Labeling conforming to 21CFR 801.109 and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions	Labeling conforming to 21CFR 801.109 and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions	No change
34.	Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1	No change

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VII. *Preclinical Data*

Performance Tests

The PINION™ PDO & PINION™ PGA-PCL Knotless Sutures were subjected to the performance testing as per FDA's Special Control Guidance Document for Surgical Sutures, '' Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff June 2, 2003'' performance testing including testing in accordance to USP for Absorbable suture and biocompatibility testing of the suture material in accordance to EN ISO 10993-1:2020 has been performed to further ensure substantial equivalence to the predicate devices. The safety and effectiveness of the PINION™ PDO & PINION™ PGA-PCL Knotless Sutures have been evaluated for the following performance and safety requirements.

1. Diameter USP <861>
2. Tensile strength USP <881>
3. Needle attachment USP <871>
4. Suture Length
5. Number of barbs per linear length of suture
6. Barb size (length)
7. Barb size Direction
8. Barb Angle
9. Barb holding strength
10. Sterility USP <71>
11. Biocompatibility as per ISO 10993-1

Biocompatibility

The biocompatibility evaluation for PINION™ PDO & PINION™ PGA-PCL Knotless Suture was conducted in accordance with Guidance document 'Use of International Standard ISO 10993-1, ''Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'' September 8, 2023 and International Standards ISO 10993-1 "Biological evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process" as recognized by FDA. Biocompatibility testing performed on suture material type for implantable material included Cytotoxicity, Skin Sensitization, Irritation test, Systemic Toxicity, Genotoxicity Study, In

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vitro Haemolysis test, Implantation test, Material mediated Pyrogenicity, Chronic Toxicity and Carcinogenicity.

The risk assessment for chronic toxicity and carcinogenicity for subject device was evaluated based on the previously 510(K) cleared device (K172659).

The test results and risk assessment suggests that the subject device is biocompatible.

VIII. ***Conclusion***

PINION™ PDO & PINION™ PGA-PCL Knotless Sutures are substantially equivalent to currently marketed device and present no substantial differences in design, material, intended use and function to predicate device.

The performance, biocompatibility, sterilization, packaging and shelf life study conducted on PINION™ PDO & PINION™ PGA-PCL Knotless Sutures demonstrated the device is as safe and as effective as the predicate device. Hence, PINION™ PDO & PINION™ PGA-PCL Knotless Sutures will perform as intended in the specified use conditions.