September 23, 2025

M/s. Meril Endo Surgery Private Limited
Umesh Sharma
Senior General Manager - Quality Assurance/Regulatory Affairs
Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2
Vapi, Gujarat 396191
India

Re: K252644
Trade/Device Name: PINION™ PDO Knotless Suture - Absorbable Poly (P-Dioxanone) Knotless Suture; PINION™ PGA-PCL Knotless Suture - Absorbable 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
Dated: August 18, 2025
Received: August 21, 2025

Dear Umesh Sharma:

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.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K232246

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

PINION™ PDO Knotless Suture is 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 soft tissue approximation where use of an absorbable suture is appropriate.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

(K252644)

I. *SUBMITTER*

M/s. Meril Endo Surgery Private Limited.
Third Floor, E1 – E3, Meril Park,
Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi – 396191 Gujarat, India.
Tel. No: +91-260-3052100, Fax: +91-260-3052125
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Applicant Information

Mr. Umesh Sharma
Senior General Manager – Quality Assurance / Regulatory Affairs
E-mail: umesh.sharma@merillife.com

Primary Correspondent Information

Mr. Umesh Sharma
Senior General Manager – Quality Assurance / Regulatory Affairs
E-mail: umesh.sharma@merillife.com

Date Prepared: September 22nd, 2025

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

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

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III. *PREDICATE DEVICE*

Subject device	Predicate device		
	Trade Name/Proprietary Name	**Predicate Device Name**	**510 (K) No.**
PINION™ PDO Knotless Suture - Absorbable Poly (P-Dioxanone) Knotless Suture	PINION™ PDO Knotless Suture	PINION™ PDO Knotless Suture - Absorbable Poly (P-Dioxanone) Knotless Suture	K232246
PINION™ PGA-PCL Knotless Suture - Absorbable Poly (Glycolide-Co-Caprolactone) Knotless Suture	PINION™ PGA-PCL Knotless Suture	PINION™ PGA-PCL Knotless Suture - Absorbable Poly (Glycolide-Co-Caprolactone) Knotless Suture	K232246

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) 5-0 (1), 4-0 (1.5), 3-0 (2), 2-0 (3), 0 (3.5), 1 (4) & 2(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 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

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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)
5-0	4-0	5-0/0.68
4-0	3-0	4-0/0.95
3-0	2-0	3-0/1.77
2-0	0	2-0/2.68
0	1	0/3.90
1	2	1/5.08
2	3	2/6.35

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)
5-0	0.100-0.149	0.150-0.199
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
0	0.350-0.399	0.400-0.499
1	0.400-0.499	0.500-0.599
2	0.500-0.599	0.600-0.699

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).

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) 0 (3.5), 1 (4)

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& 2(5). 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
0	1	0/3.90
1	2	1/5.07
2	3	2/6.35

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
0	0.350-0.399	0.400-0.499
1	0.400-0.499	0.500-0.599
2	0.500-0.599	0.600-0.699

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

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 predicate device. The subject device maintain the same intended use, material composition, mechanism of action, fundamental technology, performance characteristics and packaging configuration.

The only modification introduced in this submission is the expansion of available suture sizes. For these additional suture sizes, all testing was performed in accordance with applicable USP and ASTM standards, as well as validated in-house methods, and the results met pre-defined acceptance criteria.

Furthermore, Biological Safety, Shelf-Life and Packaging Integrity, Labeling, and Sterility remain unchanged from the predicate devices, as no modifications were made in these aspects.

Therefore, the expanded size range performs equivalently to the cleared predicate devices and does not raise the questions of safety and effectiveness.

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

510(K) SUMMARY

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	PINION™ PDO Knotless Suture	-
2.	Manufacturer	Meril EndoSurgery Pvt. Ltd.	Meril EndoSurgery Pvt. Ltd.	-
3.	510(K) Number	-	K232246	-
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	21 CFR 878.4840	21 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.	**PINION™ PDO Knotless Suture** is indicated for use in general soft tissue approximation where use of an absorbable suture use is appropriate.	No Change
9.	Device Description	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	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	Only addition of suture sizes as per USP.

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
		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) 5-0 (1), 4-0 (1.5), 3-0 (2), 2-0 (3), 0 (3.5), 1 (4) & 2(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 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	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 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	

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
		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 PINION™ PDO Knotless Suture is MR Safe.	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 PINION™ PDO Knotless Suture is MR Safe.	
10.	For single use only	Single use only	Single use only	No change
11.	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 an extended healing period. The in-vitro study indicates that the PINION™ PDO Knotless Suture retains the percentage (%) of its original tensile strength as presented in Table.	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. 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	No change

510(K) SUMMARY

<table>
<tr><th>Sr. No.</th><th>Characteristics</th><th>Subject Device</th><th>Predicate Device</th><th>Safety / Effectiveness</th></tr>
<tr><td></td><td></td><td>Table: In-vitro Tensile Strength Profile
<table><tr><th>Days</th><th>Approximate Original Tensile Strength remaining Sizes 3-0 and larger</th><th>Approximate Original Tensile Strength remaining Size 4-0 & Smaller</th></tr><tr><td>14</td><td>70-80 %</td><td>50-60 %</td></tr><tr><td>28</td><td>70-80 %</td><td>40-50 %</td></tr><tr><td>42</td><td>40-50 %</td><td>15-35 %</td></tr></table>
The absorption of PINION™ PDO Knotless Suture is minimal until about 120 days and complete absorption usually takes place within 180 days (six months).</td><td>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).</td><td></td></tr>
<tr><td>12.</td><td>Material composition</td><td>poly (p-dioxanone)</td><td>poly (p-dioxanone)</td><td>No change</td></tr>
<tr><td>13.</td><td>Body Contact</td><td>Tissue/Bone/Blood</td><td>Tissue/Bone/Blood</td><td>No change</td></tr>
<tr><td>14.</td><td>Shelf Life</td><td>5 Year</td><td>5 Year</td><td>No change</td></tr>
<tr><td>15.</td><td>USP Sizes (Size availability)</td><td>5-0 to 2</td><td>3-0 to 0</td><td>The extended range of the suture size is in accordance with USP.</td></tr>
<tr><td>16.</td><td>Absorbable/Non Absorbable</td><td>Absorbable</td><td>Absorbable</td><td>No change</td></tr>
<tr><td>17.</td><td>Braided/</td><td>Monofilament</td><td>Monofilament</td><td>No change</td></tr>
</table>

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Sr. No.	Characteristics	Subject Device		Predicate Device		Safety / Effectiveness
	Monofilament					
18.	Dyed / Undyed	Undyed or Dyed Suture Strands		Undyed or Dyed Suture Strands		No change
19.	Colorant	D&C Violet No. 2		D&C Violet No. 2		No change
20.	Coated / Uncoated	Uncoated		Uncoated		No change
21.	Types of Barbs	Uni-directional, Bi-directional		Uni-directional, Bi-directional		No change
22.	Barb Angle	5-0	45-55**(∠˚)**	-	-	The extended range of the suture size is in accordance with USP. Additional testing is conducted for additional sizes.
		4-0	58-63 **(∠˚)**	-	-	
		3-0	35-45 **(∠˚)**	3-0	35-45 **(∠˚)**	
		2-0	40-50 **(∠˚)**	2-0	40-50 **(∠˚)**	
		0	35-45 **(∠˚)**	0	35-45 **(∠˚)**	
		1	45-55**(∠˚)**	-	-	
		2	45-55**(∠˚)**	-	-	
23.	Barb Height	5-0	0.200-0.300 mm	-	-	The extended range of the suture size is in accordance with USP. Additional testing is conducted for additional sizes.
		4-0	0.258-0.283 mm	-	-	
		3-0	0.250-0.350 mm	3-0	0.250-0.350 mm	
		2-0	0.300-0.400 mm	2-0	0.300-0.400 mm	
		0	0.350-0.450 mm	0	0.350-0.450 mm	
		1	0.400-0.500 mm	-	-	
		2	0.450-0.550 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
27.	Complete Absorption	within 180 to 210 days		within 180 to 210 days		No change
28.	Sterilization method	Ethylene Oxide		Ethylene Oxide		No change

510(K) SUMMARY

Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
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.	No change
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.	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.	No change
	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	Labeling conforming to 21CFR 801.109	Labeling conforming to 21CFR 801.109	No change

510(K) SUMMARY

Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
	for use (IFU).	and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions.	and USP. IFU includes indications, warnings, adverse reactions, Contraindication and precautions	
34.	Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	No change

Table 2: PINION™ PGA-PCL Knotless Suture

Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
1.	Device Name	PINION™ PGA PCL Knotless Suture	PINION™ PGA PCL Knotless Suture	-
2.	Manufacturer	Meril EndoSurgery Pvt. Ltd.	Meril EndoSurgery Pvt. Ltd.	-
3.	510(K) Number	-	232246	-
4.	Common Name	Absorbable poly(glycolide/l-lactide) surgical suture	Absorbable poly(glycolide/l-lactide) surgical suture	No change
5.	Class	II	II	No change
6.	Product Code	GAM	GAM	No change
7.	Regulation Number	21 CFR 878.4493	21 CFR 878.4493	No change
8.	Intended use	PINION™ PGA PCL Knotless Suture is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate.	PINION™ PGA PCL Knotless Suture is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate.	No change
9.	Device Description	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.	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,	Only addition of suture sizes as per USP.

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
		PINION™ PGA-PCL Knotless Suture is a sterile, synthetic, absorbable monofilament suture comprised of poly (glycolide-co-caprolactone). 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) 0 (3.5), 1 (4) & 2(5). 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	synthetic, absorbable monofilament suture comprised of poly (glycolide-co-caprolactone). 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	

510(K) SUMMARY

Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
		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 PINION™ PGA-PCL Knotless Suture is MR Safe.	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 PINION™ PGA-PCL Knotless Suture is MR Safe.	
10.	For single use only	Single use only	Single use only	No change
11.	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).	Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). PINION™ PGA PCL Knotless Suture has been formulated to	No change

510(K) SUMMARY

<table>
<tr><th>Sr. No.</th><th>Characteristics</th><th>Subject Device</th><th>Predicate Device</th><th>Safety / Effectiveness</th></tr>
<tr>
<td></td>
<td></td>
<td>PINION™ PGA PCL Knotless Suture 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.

The In-vitro study indicates that the PINION™ PGA-PCL Knotless Suture retains the percentage (%) of its original tensile strength as presented in Table.

Table: In-vitro Tensile Strength Profile

<table>
<tr><th colspan="2">Approximate Original Tensile Strength remaining Sizes 3-0 and larger</th><th colspan="2">Approximate Original Tensile Strength remaining Size 4-0</th></tr>
<tr><td>Days</td><td></td><td>Days</td><td></td></tr>
<tr><td>7</td><td>62 %</td><td>7</td><td>60 %</td></tr>
<tr><td>14</td><td>46 %</td><td>14</td><td>42 %</td></tr>
<tr><td colspan="2">All of the original tensile strength is essentially lost</td><td colspan="2">All of the original tensile strength is essentially lost</td></tr>
</table>
</td>
<td>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 % 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></td>
</tr>
</table>

510(K) SUMMARY

Sr. No.	Characteristics	Subject Device		Predicate Device		Safety / Effectiveness
		by 28 days. **by 21 days.** The absorption of PINION™ PGA-PCL Knotless Suture is essentially completed between 90 and 120 days.				
12.	Material composition	Copolymer of (glycolide and ε carprolactone)(PGA-PCL)		Copolymer of (glycolide and ε carprolactone)(PGA-PCL)		No change
13.	Body Contact	Tissue/Bone/Blood		Tissue/Bone/Blood		No change
14.	Shelf Life	5 Year		5 Year		No change
15.	Size availability	4-0 to 2		4-0 to 2-0		The extended range of the suture size is in accordance with USP.
16.	Absorbable/Non Absorbable	Absorbable		Absorbable		No change
17.	Braided/ Monofilament	Monofilament		Monofilament		No change
18.	Dyed / Undyed	Undyed or Dyed Suture Strands		Undyed or Dyed Suture Strands		No change
19.	Colorant (if Dyed)	D&C Violet No. 2		D&C Violet No. 2		No change
20.	Coated / Uncoated	Uncoated		Uncoated		No change
21.	Types of Barbs	Uni-directional, Bi-directional		Uni-directional, Bi-directional		No change
22.	Barb Angle	4-0	58-63 **(∠˚)**	4-0	58-63 **(∠˚)**	The extended range of the suture size is in accordance with USP. Additional testing is conducted for additional sizes.
		3-0	35-45 **(∠˚)**	3-0	35-45 **(∠˚)**	
		2-0	40-50 **(∠˚)**	2-0	40-50 **(∠˚)**	
		0	35-45 **(∠˚)**	-	-	
		1	45-55**(∠˚)**	-	-	
		2	45-55**(∠˚)**	-	-	
23.	Barb Height	4-0	0.253-0.283 mm	4-0	0.253-0.283 mm	The extended range of the suture size is in
		3-0	0.250-0.350 mm	3-0	0.250-0.350 mm	
		2-0	0.300-0.400 mm	2-0	0.300-0.400 mm	

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Sr. No.	Characteristics	Subject Device		Predicate Device		Safety / Effectiveness
		0	0.350-0.450 mm	-	-	accordance with USP. Additional testing is conducted for additional sizes.
		1	0.400-0.500 mm	-	-	
		2	0.450-0.550 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
27.	Absorption Profile	between 90 and 120 days.		between 90 and 120 days.		Identical
28.	Sterilization method	Ethylene Oxide		Ethylene Oxide		Identical
29.	Needle Material	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 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.		No Change
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.		No change
	Tensile strength USP <88I>	Finished suture material meets the performance requirements defined		Finished suture material meets the performance requirements defined in the		No change

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Sr. No.	Characteristics	Subject Device	Predicate Device	Safety / Effectiveness
		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.	United States Pharmacopeia for Tensile strength <881>. Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures for same suture size equivalent.	
	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

510(K) SUMMARY

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
12. Suture Resorption Profile

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 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.

510(K) SUMMARY

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.