July 12, 2024

Peters Surgical
℅ Marie Compagnon Riobé
Chief Sustainability and Regulatory Officer
Peter Surgical
119 North Road
Deerfield, New Hampshire 03037

Re: K232372
Trade/Device Name: Peters Surgical ADVANTIME Absorbable Suture (ADVANTIME)
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: June 3, 2024
Received: June 3, 2024

Dear Marie Compagnon Riobé:

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: 2024.07.12 13:49:55 -04'00'

Tek N. Lamichhane, Ph.D.
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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)*

K232372

Device Name

Peters Surgical ADVANTIME Absorbable Suture (ADVANTIME)

Indications for Use *(Describe)*

ADVANTIME® synthetic absorbable surgical sutures are intended for use in general soft tissue approximation and/or ligation, but not for use cardiovascular surgery, microsurgery, ophthalmic surgery, and neurological tissue.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary-K232372

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of ADVANTIME® Device.

1. Applicant

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3. Regulatory Correspondent/ 510(k) Submission Contact

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4. Date Prepared: July 12, 2024

5. Device Information

Device: Peters Surgical ADVANTIME Absorbable Suture (ADVANTIME)
Panel: General and Plastic Surgery
Regulatory Number: 21 CFR 878.4493
Product Code: GAM
Device Class: Class II

6. Predicate Device

DemeCaprone (Poliglecaprone 25) Synthetic Monofilament (PGCL) Absorbable Suture (K130083)

7. Device Description

ADVANTIME® sutures are intended to be used in suturing and/or tissue ligation in open or laparoscopic surgery. These sutures are available with a disposable needle attachment.

ADVANTIME® is a single use, sterile, single-stranded (monofilament), synthetic bioabsorbable thread made of a poliglecaprone (a copolymer of glycolide and E- caprolactone of low tissue reactivity). Sutures are commonly used in digestive, urological, aesthetic, gynecological and intradermal surgery. To perform suturing on soft tissue wounds involves a series of precise steps. The surgeon grasps the needle, pushes it through tissue, pulls it through and repeats for continuous suturing. The same applies to double-armed needles. Further, knots are tied, excess thread is cut, and used needles are single use and safely disposed in accordance with hospital procedure.

8. Indications for Use

ADVANTIME® synthetic absorbable surgical sutures are intended for use in general soft tissue approximation and/or ligation, but not for use cardiovascular surgery, microsurgery, ophthalmic surgery, and neurological tissue.

9. Comparison of Technological Characteristics

The ADVANTIME® device is substantially equivalent in intended use, design, performance, and principle of operation to the predicate device – DemeCaprone (K130083). Both devices include similar components of thread that are attached with needles. The ADVANTIME® and the predicated device consist of the same technological characteristics and are available in similar configurations and materials. Below the comparison table specifies substantial equivalence comparison between proposed device and predicated device. Any differences between ADVANTIME® and DemeCaprone sutures and needles are insignificant and do not raise any issues regarding safety or performance of the ADVANTIME® device.

Below is a comparison table that provides a top-level overview of the substantial equivalent comparison between proposed and predicate devices.

Comparative Characteristics	Proposed Device: ADVANTIME®	Predicate Device: DemeCaprone
General Information		
510(k) Number	K232372	K130083
Classification	General and Plastic Surgery	General and Plastic Surgery
Device Description	ADVANTIME® suture is a synthetic monofilament absorbable surgical sutures composed of Poly(glycolic-co-caprolactone) copolymer (PGCL) and is supplied undyed and	DemeCaprone (Poliglecaprone 25) suture is a synthetic monofilament absorbable surgical suture composed of Poly (glycolic-co-caprolactone) copolymer (PGCL) and

	dyed with D&C Violet #2 below 0.1%	is supplied un-dyed and dyed with D&C Violet #2 below 0.1%
Product Code	GAM	GAM
Indication for Use/Intended Use	ADVANTIME® synthetic absorbable surgical sutures are intended for use in general soft tissue approximation and/or ligation, but not for use cardiovascular surgery, microsurgery, ophthalmic surgery, and neurological tissue.	DemeCaprone (Poliglecaprone 25) Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use cardiovascular, surgery, microsurgery, ophthalmic surgery, and neurological tissue.
Regulation Number	21 CFR 878.4493	21 CFR 878.4493
Regulatory Class	Class II	Class II
Surgical approach	In open or laparoscopic surgery	In open or laparoscopic surgery
Principle Device Components (Sterile, Disposable and Single Use)	Thread with attached needle	Thread with or without attached needle
Type of Device (Material Used)	Absorbable Poly(glycolic-co-caprolactone) sutures	Absorbable Poly(glycolic-co-caprolactone) sutures
Biocompatibility requirements	ISO 10993	ISO 10993
Sterilization methods	Ethylene Oxide method	Ethylene Oxide method
Technical Features/Design		
Thread material	Poly(glycolide-co-caprolactone)	Poly(glycolide-co-caprolactone)
Dyed of thread	Dyed or Undyed	Dyed or Undyed
Thread coating	No coating	No coating
Thread size (diameter)	USP 6/0 to USP 1	USP 6/0 to USP 1
Thread length	45 cm to 110 cm	45 cm to 150 cm
Dyeing of thread	Undyed, Dyed (D&C Violet #2 below 0.1%)	Undyed, Dyed (D&C Violet #2 below 0.1%)
Needle material	Stainless steel	Stainless steel
Needle coating	Silicone coating	Information not available
Needle curvatures	½, 3/8, 5/8, and straight	½, 3/8, 5/8, and straight
Needle points	Cutting, taper cutting, taper and extracut	Reverse cutting, taper cutting, curved cutting, round bodied, and blunt point
Needle length	10 mm to 60 mm	11 mm to 70 mm
Absorption time	Between 90 to 120 days	Between 90 to 120 days
Shelf-life	5 years	Information not available
Ideal storage	Must be stored in its original packaging, at a temperature below 25°C, in a dry place	Must be stored at room temperature

10. Summary of Testing

As per the FDA's Class II Special Control Guidance Document for Surgical Sutures, the subject device was subjected to the requirements of the United States Pharmacopeia (U.S.P) monograph for Synthetic Absorbable Sutures.

Testing included:

- Diameter following USP 43 <861>
- Tensile strength following USP 43 <881>
- Needle attachment following USP 43 <871>
- Length following USP 43- Absorbable surgical suture
- Extractable color following USP 43- Absorbable surgical suture

Resorption profiles have been evaluated for each material. Resorption data in-vitro was provided for ADVANTIME® and DemeCaprone.

Stability testing has been completed.

Results of USP performance and resorption testing demonstrate that the subject device meets USP performance requirements for absorbable sutures with the exception of minor variations in diameter (with FDA guidance allowance) from USP and is substantially equivalent to the predicate device listed.

The biological evaluation of ADVANTIME® was performed in accordance with FDA guidance on the use of ISO 10993-1. The following test reports were provided in this submission:

- Cytotoxicity
- Sensitization
- Irritation
- Material mediated pyrogenicity
- Acute Systemic Toxicity
- Sub-acute/sub-chronic/chronic toxicity
- Genotoxicity
- Carcinogenicity
- Chemical characterization and toxicological risk assessment
- Implantation
- Degradation
- Sterilization residue testing

11. Conclusion:

Based on the information provided within this 510(k) submission, Peters Surgical concludes that the **Peters Surgical ADVANTIME Absorbable Suture (ADVANTIME)** is substantially equivalent to the predicate device, DemeCaprone (Poliglecaprone 25) Synthetic Monofilament (PGCL) Absorbable Suture (K130083).