May 10, 2024

Threadstone L.L.C.
Jeremy Clark
President
1035 Benfield Blvd, Suite H
Millersville, Maryland 21108

Re: K234079
Trade/Device Name: HyperSuture Extension Line
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: April 9, 2024
Received: April 9, 2024

Dear Jeremy Clark:

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: 2024.05.10 12:17:20 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234079

Device Name

HyperSuture Extension Line

Indications for Use *(Describe)*

HyperSuture Extension Line (both tape and cable) are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular procedures, and the use of allograft tissue for orthopedic procedures.

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.

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510(k) Summary

510(k) Summary of Threadstone HyperSuture™ Extension Line (K234079)

Submitter Information

Applicant:	Threadstone L.L.C.
Address:	1035 Benfield Blvd, Suite H, Millersville, MD 21163, USA
Phone Number:	443-790-6536
Fax Number:	N/A
Registration Number:	3017499940
Contact Person:	Jeremy Clark Office@Threadstoneusa.com
Date of Preparation:	08MAY2024

Device Name

Trade Name:	HyperSuture™ Extension Line
Common or Usual Names:	Polyblend Suture, Non-absorbable Surgical Sutures
Classification Name:	Nonabsorbable poly(ethylene terephthalate) Surgical Suture

Device Classification

FDA Class:	II
Product Classification:	21 CFR 878.5000 Suture, nonabsorbable, synthetic, polyethylene
Classification Code:	GAT
Review Panel:	General & Plastic Surgery
Premarket Review:	Office of Device Evaluation Division of Surgical Devices, Plastic and Reconstructive General Surgery Devices Branch

Predicate Device	K230311 – HyperSuture™ (GAT – 21 CFR 878.5000 Suture, nonabsorbable, synthetic, polyethylene)

510(k) Summary

Device Description Summary:
HyperSuture Extension Line cables are non-absorbable, sterile, surgical sutures composed of multiple multifilament strands of ultra-high molecular weight polyethylene (UHMWPE) braided together to form the implant. The sutures are intended to be used for general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and allograft tissues for orthopedic procedures. HyperSuture Extension Line cables are available in USP 2 and USP 5 and tapes are available in 1.5 (USP 2 equivalent) and 2.5 (USP 5 equivalent). Both HyperSuture Extension Line cables and tapes are available in white/blue, 40 inches in length, and with or without pre-attached AISI 302 stainless steel needles.

Intended Use / Indication for Use:
HyperSuture Extension Line sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues for orthopedic procedures.

Substantial Equivalence Summary:
The Threadstone HyperSuture Extension Line devices are substantially equivalent to the predicate devices as the features and intended uses are the same. The HyperSuture Extension Line devices have the same principles of operation and similar technical characteristics as the predicate device. Biocompatibility testing and mechanical testing have been conducted, including implantation studies, chemical characterization, toxicology assessments, length, diameter, tensile strength, and needle attachment strength, to demonstrate that the proposed product has met the acceptance criteria for the proposed indications.

Technical Characteristic Comparison Chart:

Characteristics	Subject Device	Predicate Device	Substantial Equivalence
	HyperSuture™ Extension Line	HyperSuture™	
510(k) Number	K234079	K230311	N/A
Product Code	GAT	GAT	Identical

510(k) Summary

Regulation No.	21 CFR 878.5000 Suture, nonabsorbable, synthetic, polyethylene	21 CFR 878.5000 Suture, nonabsorbable, synthetic, polyethylene	Identical
Class	II	II	Identical
Sterile	Yes (EO Sterilization)	Yes (EO Sterilization)	Identical
Single Use	Yes	Yes	Identical
Indication for Use	For use in general soft tissue approximation and/or ligation, including use in cardiovascular, and the use of allograft tissue for orthopedic procedures.	For use in general soft tissue approximation and/or ligation, including use in cardiovascular, and the use of allograft tissue for orthopedic procedures.	Identical
Configurations	Cable and Tape with or without needle attached	Cable and Tape with or without needle attached	Identical
Cable Material	White/Blue (Total 18 yarns) Cables are made from sixteen (16) UHMWPE yarns with two (2) 20 denier UHMWPE yarns	White/Black (Total 18 yarns) Cables are made from fourteen (14) UHMWPE yarns and two (2) Nylon yarns with two (2) 20 denier UHMWPE yarns All White (Total 18 yarns) Cables are made from sixteen (16) UHMWPE yarns with two (2) 20 denier UHMWPE yarns	Yes, the number of UHMWPE yarns is identical to that of the All White configuration. Eighteen (18) Total.
Tape Material	White/Blue (Total 17 yarns) Tapes are made from seventeen (17) UHMWPE	White/Black (Total 17 yarns) Tapes are made fifteen (15) UHMWPE yarns and two (2) Nylon yarns All White (Total 17 yarns) Tapes are made from seventeen (17) UHMWPE	Yes, the number of UHMWPE yarns is identical to that of the All White configuration. Seventeen (17) Total.
Cable Denier Selection	Denier used in the suture is determined by the USP size of the suture.	Denier used in the suture is determined by the USP size of the suture.	Identical

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Tape Denier Selection	Denier used in the suture is determined by the USP size equivalent of the suture tape. Ex. USP #2 (1.5 tape) and USP #5 (2.5 tape)	Denier used in the suture is determined by the USP size equivalent of the suture tape. Ex. USP #2-0 (0.5 tape), USP #2 (1.5 tape) and USP #5 (2.5 tape)	Identical, this submission will not include the USP 2-0 size
Dye Information	Blue is [Phthalocyaninato (2-)] copper < 0.5% by weight per 21 CFR 74.3045 White UHMWPE is raw/natural.	Black is Logwood Extract < 1.0% by weight per 21 CFR 73.1410. White UHMWPE is raw/natural.	The candidate device uses blue dye which is made of [Phthalocyaninato (2-)] copper < 0.5% by weight per 21 CFR 74.3045 dye. This has been tested for biocompatibility. White UHMWPE is raw/natural and identical in both the predicate and candidate device.
Coating Material	Uncoated	Uncoated	Identical
Absorbability	Nonabsorbable	Nonabsorbable	Identical
Braided/ Monofilament	Braided	Braided	Identical
Tape Construction	Suture Tapes are made of three distinct segments: cable section, tape section, followed by another cable section so that each section is a third of the length of the suture tape. Cable sections conform to USP diameter requirements. Tape sections have a rectangular cross-section that does not comply with USP diameter requirements.	Suture Tapes are made of three distinct segments: cable section, tape section, followed by another cable section so that each section is a third of the length of the suture tape. Cable sections conform to USP diameter requirements. Tape sections have a rectangular cross-section that does not comply with USP diameter requirements.	Identical
Sizes	Suture Cable Configuration: USP #2, USP #5 Suture Tape Configuration: Tape 1.5: Cable sections – USP #2 Tape section width – 1.3mm ~1.6mm	Suture Cable Configuration: USP 2-0, USP #2, USP #5 Suture Tape Configuration: Tape 0.5: Cable sections – USP 2-0	Identical, this submission will not include the USP 2-0 size

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	Tape 2.5 Cable sections – USP #5 Tape sections – 1.9mm ~ 2.3 mm	Tape section width – 0.7mm ~ 0.85 mm Tape 1.5: Cable sections – USP #2 Tape section width – 1.3mm ~1.6mm Tape 2.5 Cable sections – USP #5 Tape sections – 1.9mm ~ 2.3 mm	
Length of Suture	40-inch	40-inch	Identical
Finish	Heat-stiffened	Heat-stiffened	Identical
Needle Material	AISI 302 Medical Grade Stainless Steel per ASTM F899	AISI 302 Medical Grade Stainless Steel per ASTM F899	Identical
Needle Type	½ Circle, Trocar Point	½ Circle, Trocar Point	Identical
Diameter of Suture Cables and Suture Cable Sections	The suture diameters of the proposed devices comply with the diameter requirements listed in USP 43 <861> Sutures – Diameter with the exception of the tape section of the suture tape.	The suture diameters of the proposed devices comply with the diameter requirements listed in USP 43 <861> Sutures – Diameter with the exception of the tape section of the suture tape.	Identical
Tensile Strength	Both cables and tapes comply with the tensile strength requirements listed in USP 43 <881> Tensile Strength.	Both cables and tapes comply with the tensile strength requirements listed in USP 43 <881> Tensile Strength.	Identical
Needle Attachment	The needle attachment strengths between suture and needle of the applicable devices (suture and tape) comply with the needle attachment strength requirements listed in USP 43 <871> Sutures - Needle Attachment.	The needle attachment strengths between suture and needle of the applicable devices (suture and tape) comply with the needle attachment strength requirements listed in USP 43 <871> Sutures - Needle Attachment.	Identical

510(k) Summary

Device Comparison Discussion:
Substantial equivalence between the Threadstone HyperSuture Extension Line and the Threadstone HyperSuture (K230311) can be demonstrated according to the FDA's guidelines for substantial equivalence decision making process for at least the following reasons:

1. The Threadstone HyperSuture Extension Line has equivalent intended use and indications as the Threadstone HyperSuture (K230311)
2. Major technological characteristics are substantially equivalent between the Threadstone HyperSuture Extension Line and the Threadstone HyperSuture including, but not limited to:
    a. Substantially equivalent materials
    b. Substantially equivalent size range
    c. Substantially equivalent method of use
    d. Substantially equivalent mechanical strength

The Threadstone HyperSuture (K230311) are also made from UHMWPE material (raw/white) and/or a combination of UHMWPE material (raw/white) and Nylon (black). The Threadstone HyperSuture extension line is made from a combination of UHMWPE material (raw/white) and UHMWPE (Blue Dye: [Phthalocyaninato(2-)] copper) which has been evaluated for biocompatibility by trained, board certified veterinary pathologists.

Non-Clinical Testing Summary:
The Threadstone HyperSuture™ Extension Line sutures (both cables and tapes) meet requirements established by the United States Pharmacopeia (USP). The HyperSuture Extension Line sutures were tested per USP performance requirements for diameter, length, needle attachment and tensile strength. Materials were evaluated per ISO 10993-1:2009 – Biological Evaluation of Medical Devices. The Threadstone HyperSuture™ Extension Line products demonstrated substantial equivalence to the Threadstone HyperSuture™ products.

Conclusion:
Based on the results of completed performance testing inclusive of physical testing, biocompatibility testing, it can be concluded that the Threadstone HyperSuture™ Extension Line is substantially equivalent in terms of safety and effectiveness to HyperSuture™.