November 24, 2023

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

Re: K230311
Trade/Device Name: HyperSuture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: October 25, 2023
Received: October 26, 2023

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: 2023.11.24 07:54:48 -05'00'

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.

510(k) Number *(if known)*
K230311

Device Name
HyperSuture

Indications for Use *(Describe)*
HyperSuture sutures (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.

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510(k) Summary of Threadstone HyperSuture (K230311)

1. Submitter Information

Submitter's Name:	Threadstone L.L.C.
Address:	1035 Benfield Blvd, Suite H, Millersville, MD 21163, USA
Phone Number:	(410) 544-2833
Fax Number:	N/A
Registration Number:	3017499940
Contact Person:	Jeremy Clark, Office@Threadstoneusa.com

Date of Preparation:	11/22/2023

2. Device Name

Trade Name:	HyperSuture™
Common or Usual Names:	Polyblend Suture, Non-absorbable Surgical
Sutures Classification Name:	Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture

3. Device Classification

FDA Class:	II
Product Classification:	21CFR §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

4. Predicate Device

K181774 – Force Fiber Suture and Force Fiber OrthoTape Suture

5. Device Description

HyperSuture 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. HyperSuture cables are available in USP 2-0, USP 2, and USP 5 and meet all surgical suture requirements established by the USP for class II non- absorbable surgical sutures.

HyperSuture tapes are non-absorbable, sterile, braid for surgery composed of multiple multifilament strands of ultra-high molecular weight polyethylene (UHMWPE) braided together to form the implant. HyperSuture tape sizes do not conform to USP diameter requirements; however, HyperSuture tapes meet USP tensile strength and needle attachment strength requirements for equivalent USP size sutures. HyperSuture tape sizes are available in Threadstone tape size 0.5 (USP 2-0 equivalent), tape 1.5 (USP 2 equivalent), and tape 2.5 (USP 5 equivalent).

Both HyperSuture cables and tapes are available in white and white/black, 40 inches in length, and with or without pre-attached needles.

6. Intended Use / Indication for Use

HyperSuture sutures (both cables and tapes) 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.

7. Substantial Equivalence and Comparison of Technical Characteristics

HyperSuture product family is substantially equivalent to the previously cleared Force Fiber Suture and Force Fiber OrthoTape. The HyperSuture product family has the same intended use and indications for use, the same principles of operation, and similar technical characteristics as the predicate device, Force Fiber Suture and Force Fiber OrthoTape cleared per K181774. Both the HyperSuture and the predicate device are sterilized using the same processes (EO Sterilization), are composed of the same material (UHMWPE), and are tested per USP performance requirements for length, tensile strength and needle attachment. The minor differences in technical characteristics are limited to the needle material, needle shapes and needle tips. The HyperSuture product family utilizes AISI 302 stainless steel needle with 1/2 circle curvature and taper cutting which is a subset of needle shape and tips provided by the predicate sutures. These differences do not raise new questions of safety or effectiveness as it will be discussed in the performance data; therefore, the HyperSuture suture product family is substantially equivalent to the currently marketed predicate device.

8. Performance Data

HyperSuture sutures (both cables and tapes) meet requirements established by the United States Pharmacopeia. HyperSuture cables are tested per USP performance requirements for diameter, needle attachment and tensile strength. HyperSuture tapes are tested per USP performance requirements for tensile strength and needle attachment strength and Threadstone specifications for the tape width. FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission. Materials used were evaluated per ISO 10993-1:2018 – Biological Evaluation of Medical Devices. Limulus Amebocyte Lysate (LAL) endotoxin quantification assessments, both process validation and routine testing, demonstrate endotoxin quantities below the recommended limits outlined in FDA Guidance "Pyrogens and Endotoxins Testing: Questions and Answers."

9. Conclusion

The information provided in this 510(k) demonstrates that HyperSuture™ (K230311) is substantially equivalent to the predicate sutures cleared under K181774.