March 27, 2025

Threadstone LLC
Jeremy Clark
President
1035 Benfield Blvd
Suite H
Millersville, Maryland 21108

Re: K242201
Trade/Device Name: HyperSuture™ White/Green Extension Line
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 26, 2024
Received: July 26, 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.

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 Infection Control
and Plastic and Reconstructive Surgery Devices
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and Infection Control Devices
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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.

510(k) Number *(if known)*
K242201

Device Name
HyperSutureTM White/Green Extension Line

Indications for Use *(Describe)*
HyperSuture™ White/Green 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.

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 -K242201

510(k) Summary of Threadstone HyperSuture™ White/Green Extension Line

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:	26JUL2024

Device Name

Trade Name:	HyperSuture™ White/Green 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™ White/Green 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™ White/Green Extension Line cables are available in USP #2-0, USP #2, and USP #5 and tapes are available in 0.8mm (USP 2-0 equivalent), 1.5mm (USP 2 equivalent) and 2.0mm (USP 5 equivalent). Both HyperSuture™ White/Green Extension Line cables and tapes are available in white/green, 36 inches or 40 inches in length, and with or without pre-attached AISI 302 stainless steel needles.

Intended Use / Indication for Use:

HyperSuture™ White/Green 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 and Comparison of Technical Characteristics

The Threadstone HyperSuture™ White/Green Extension Line devices are substantially equivalent to the previously cleared Threadstone HyperSuture™ cables and tapes, cleared under K230311. The HyperSuture™ White/Green Extension Line devices have the same intended use and indications for use, the same principles of operation, and similar technical characteristics as the predicate devices. Both the HyperSuture™ White/Green Extension Line products and the predicate devices are manufactured, packaged, and sterilized at the same location, using the same process. Both are composed of the same UHMWPE material for suture and 302 AISI stainless steel for needle, and are tested per USP 43 performance requirements for diameter, tensile strength and needle attachment.

The minor differences in technical characteristics are limited to the color additive content and the tracer material. HyperSuture™ White/Green Extension Line products consist of white UHMWPE and 6-0 green polyester tracer as opposed to white UHMWPE and 6-0 black nylon-6,6 tracers in the predicate device. For 6-0 green polyester tracer, D&C Green No.6 was used less than 0.75% by weight per 21 CFR 74.3206 and test on the final white/green device was conducted to show that the electrical conductivity is less

510(k) Summary

than 2 S/m. Biocompatibility of the subject device was evaluated based on contact duration.

Other technological characteristics such as materials, dimensions, sterilization, manufacturing processes, mechanical strengths (i.e., tensile strength, and needle attachment strength), shelf-life, packaging, and labels are unchanged.

Non-Clinical Testing Summary:

The Threadstone HyperSuture™ White/Green Extension Line sutures (both cables and tapes) meet requirements established by the United States Pharmacopeia (USP). The HyperSuture™ White/Green Extension Line sutures were tested per USP performance requirements for diameter, length, needle attachment and tensile strength. Materials were evaluated per ISO 10993-1:2018 – Biological Evaluation of Medical Devices. The Threadstone HyperSuture™ White/Green 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™ White/Green Extension Line is substantially equivalent in terms of safety and effectiveness to HyperSuture™ 510(k) number K230311