



September 5, 2025

SutureTech, Inc.
Benjamin Arnold
CEO-Cor Medical Ventures
810 Laurelwood Dr
Durham, North Carolina 27705

Re: K250095

Trade/Device Name: All-Suture Dual Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 21, 2025
Received: August 21, 2025

Dear Benjamin Arnold:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

Assistant Director

DHT6C: Division of Restorative, Repair and Trauma
Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250095

Device Name

All-Suture Dual Anchor System

Indications for Use (Describe)

The SutureTech All-Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-Foot Reconstruction, Metatarsal Ligament Repair, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Repairs.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair.

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

SUBMITTER:

Company Name: SutureTech, Inc.
Address: 810 Laurelwood Drive
Durham, NC 27705
Telephone: 607.351.6131

CONTACT PERSON: Benjamin Arnold

DATE PREPARED: September 2, 2025

TRADE NAME: All-Suture Dual Anchor System

COMMON NAME: Fastener, Fixation, Nondegradable, Soft Tissue

CLASSIFICATION NAME: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

REGULATORY CLASS: II

PRODUCT CODE: MBI

SUBSTANTIAL EQUIVALENCE:

The All-Suture Dual Anchor System is substantially equivalent to the primary predicate device in all facets including function, design, performance, material, and intended use.

Primary Predicate Device: Stryker All Suture Anchors (K120509)

DEVICE DESCRIPTION:

The All-Suture Dual Anchor System is intended to fixate soft tissue to bone. The device consists of an implant and a set of single use instruments. The implant is available in two configurations to accommodate varying clinical needs: the implant may be used knotted or knotless. The implant and single use instruments are provided ethylene oxide (EO) sterilized and packaged together.

MATERIALS:

The All-Suture Dual Anchor System implant is comprised of ultra-high molecular weight polyethylene (UHMWPE).

INDICATIONS FOR USE:

The SutureTech All-Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-Foot Reconstruction, Metatarsal Ligament Repair, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Repairs.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair.

TECHNOLOGICAL CHARACTERISTICS:

The All-Suture Dual Anchor System implants are made from similar materials and have equivalent design philosophy, sizing, configurations, fixation methods, sterilization and packaging, and surgical approach to the predicate device. Any differences between the All-Suture Dual Anchor System and the predicate are considered minor and do not raise different questions concerning safety or effectiveness.

PERFORMANCE TESTING:

The following bench testing was performed on the All-Suture Dual Anchor System:

- Suture Characterization
- Insertion Testing
- Static and Cyclic Pullout Force Testing
- Biocompatibility Adoption Rationale
- EO Sterilization Validation
- Packaging Adoption Rationales

In summary, rationales and mechanical testing of the All-Suture Dual Anchor System indicated there are no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSIONS:

The All-Suture Dual Anchor System is substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices. This demonstrates that the device is as safe and effective as the predicate device.