January 23, 2025

Acumed LLC
Marina Bull
Regulatory Affairs Specialist
5885 NE Cornelious Pass
Hillsboro, Oregon 97124

Re: K243624
Trade/Device Name: Acu-Sinch Knotless Mini
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: November 22, 2024
Received: November 25, 2024

Dear Marina Bull:

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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic 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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243624

Device Name

Acu-Sinch Knotless Mini

Indications for Use *(Describe)*

Acu-Sinch Knotless Mini, when used for fixation of bone-to-bone or soft-tissue to bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Acu-Sinch Knotless Mini is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of hematoma distraction arthroplasty by providing stablization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

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

[X] 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) #: K243624

510(k) Summary

Prepared on: 2024-11-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Acumed LLC
Applicant Address	5885 NE Cornelious Pass Hillsboro OR 97124 United States
Applicant Contact Telephone	970-846-6282
Applicant Contact	Ms. Marina Bull
Applicant Contact Email	marina.bull@acumed.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Acu-Sinch Knotless Mini
Common Name	Washer, Bolt, Nut
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	888.3030
Product Code(s)	HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140328	Arthrex CMC Min Tightrope	HTN

Device Description Summary

21 CFR 807.92(a)(4)

The Acu-Sinch Knotless Mini is intended to provide fixation during the healing process of a trapeziectomy. Acu-Sinch Knotless Mini consists of two buttons, a suture strand, and instruments to aid in insertion. The buttons are manufactured from titanium alloy conforming to ASTM F1 36 (Ti-6AL-4V ELI). The suture is manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The devices are sterile and for single use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Acu-Sinch Knotless Mini, when used for fixation of bone-to-bone or soft-tissue to bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Acu-Sinch Knotless Mini is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of hematoma distraction arthroplasty by providing stablization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Acu-Sinch Knotless Mini, has been compared to the predicate device, The Arthrex CMC Mini Tightrope within the 510(k) submission. The basis of substantial equivalence for the subject device to the predicate device is their similarities in intended use, material technology, operating principles, anatomical site, for implantation, performance and design. The analysis of difference between the subject device and predicate device supports substantial equivalence as the differences do not constitute a new intended use/indications for use, and the information included within the submission demonstrated that the subject device is comparable to the predicate device and does not raise different questions of safety or effectiveness.

The Acu-Sinch Knotless Mini has the same intended use/indications for use as the Arthrex CMC Mini Tightrope. Both have two buttons and a suture when used for bone-to-bone or soft-tissue to bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Technological Comparison 21 CFR 807.92(a)(6)

The Subject Device has the same technological characteristics as the Predicate Device. Both the Subject Device and Predicate Devices make use of a suture to provide fixation between the buttons, located on the outer cortices of the thumb metacarpal and index metacarpal.
The button and suture system is used for distributing suture tension over areas of ligament or tendon repair or in the suspensory fixation of the thumb metacarpal at the base of the second metacarpal when the trapezium is removed.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Static and Dynamic fatigue testing was conducted to demonstrate that the proposed Acu-Sinch Knotless Mini performs statistically equivalent to the Predicate Device; Arthrex CMC Mini Tightrope cleared under KI 40328. Acu-Sinch Knotless Mini performed as well as, or better than the predicate device.

MRI force, torque, and image artifact testing were conducted in accordance with ASTM F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, ASTM F2119 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, ASTM F2182 Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging and ASTM F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.

Endotoxin testing (LAL and MMP) was conducted and met the requirement of <20 EU/device.

Device performance was verified following 5-year accelerated and 2-year real time testing and passed.

Clinical testing was not required to support substantial equivalence (Not Applicable).

Based on the results of the nonclinical bench testing described above, it was concluded that the Subject and Predicate Devices are equivalent in performance specifically for the intended use, hence the Subject Device was proven to be safe and effective for the indication.