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.