January 7, 2022

Acumed LLC
Janki Bhatt
Regulatory Affairs Lead
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K212990
Trade/Device Name: Acumed Ankle Syndesmosis Repair System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HTW, LXH
Dated: December 8, 2021
Received: December 9, 2021

Dear Janki Bhatt:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Limin Sun, Ph.D.
Acting 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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K212990

Device Name

Acumed Ankle Syndesmosis Repair System

Indications for Use *(Describe)*

The Acumed Ankle Syndesmosis Repair System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Acumed Ankle Syndesmosis Repair System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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.

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Acumed LLC
Applicant Address	5885 NE Cornelius Pass Road Hillsboro OR 97124 United States
Applicant Contact Telephone	503-718-8753
Applicant Contact	Ms. Janki Bhatt
Applicant Contact Email	janki.bhatt@acumed.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Acumed Ankle Syndesmosis Repair System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Washer, Bolt Nut
Regulation Number	888.3030
Product Code	HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K043248	Arthrex TightRope Syndesmosis Device	HTN
K112111	3.5mm Quick Release Drill	HTW
K133469	2.8mm Quick Release Drill	LXH

Device Description Summary

21 CFR 807.92(a)(4)

The Acumed Ankle Syndesmosis Repair System is intended to provide fixation during the healing process following a syndesmotic trauma.

The Acumed Ankle Syndesmosis Repair System contains a fibula button, a tibia button and a high strength fiber suture assembled onto a driver, and is provided in a sterile kit as two options, one with and one without a drill. The system also offers optional washers in a separate sterile kit. The driver and drill are part of the sterile kits and are not available individually.

The metal implants including the buttons and washers are manufactured from Titanium Alloy (Ti 6AL-4V ELI per ASTM F136) and the suture is manufactured from ultra-high-molecular-weight polyethylene (UHMWPE).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Acumed Ankle Syndesmosis Repair System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Acumed Ankle Syndesmosis Repair System is intended to provide fixation during the healing process following a

syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Acumed Ankle Syndesmosis Repair System has been compared to the predicate device, the Arthrex TightRope Syndesmosis Device within this 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 differences between the subject device and predicate device supports substantial equivalence as the differences do not constitute a new intended use, and the information included within the submission demonstrates that the subject device is comparable to the predicate device and does not raise different questions of safety or effectiveness.

The Acumed Ankle Syndesmosis Repair System has the same indications for use as the Arthrex TightRope Syndesmosis System. Both have two buttons and a suture intended for a flexible fixation between the distal tibia and fibula across the ankle syndesmosis. Both the predicate and subject devices are intended for single use only.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device. Both predicate and subject devices make use of a suture to provide flexible fixation between the buttons located on the outer cortices of the distal tibia and fibula. Both the subject and predicate device deposit the tibial button on the outer tibial cortex through a bone hole that has been drilled from the lateral side. Although the mechanism of deposit varies between the predicate and subject devices, the final construct of the implant placement is the same between the predicate and subject devices

The Acumed Ankle Syndesmosis Repair System buttons are made of the same material as the buttons in the Arthrex TightRope Syndesmosis Device, titanium alloy (Ti-6Al-4V per ASTM F136). Both predicate and subject devices make use of a UHMWPE suture.

The subject device incorporates the same basic design as the predicate device. In each device, a tibial button is configured in an oblong shape to be passed through a 3.5 mm drill hole to be installed on the outer tibial cortex with two flat wings on either side of a suture retaining feature. In each device, the fibula button is configured in a primarily round design to be installed on the outer fibula cortex and is sized to be compatible with various plates used in fibula fracture fixation. The dimensions of each button are comparable, resulting in no difference in performance between the predicate and subject devices.

Some minor differences exist in the basic shape, design, and technology; however, the performance evaluation demonstrates that the subject device is equivalent to the predicate device

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 Acumed Ankle Syndesmosis Repair System performs statistically equivalent to the predicate device, Arthrex TightRope Syndesmosis System cleared under K043248. Additionally, insertion testing was done to confirm that the subject device performed adequately per the indication.

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.

Shelf-life was confirmed by performing accelerated aging per ASTM F1980, followed by performance evaluation of the aged device and packaging.

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.