December 29, 2022

Acumed LLC
Saleh Amirriyazi
Regulatory Affairs Specialist
5885 NE Cornelius Pass Rd.
Hillsboro, Oregon 97124

Re: K221333
Trade/Device Name: Acumed Acutrak System, Acumed Acturak 2 System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 5, 2022
Received: May 9, 2022

Dear Saleh Amirriyazi:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

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)*

K221333

Device Name

Acumed Acutrak System
Acumed Acturak 2 System

Indications for Use *(Describe)*

Acutrak Fusion, Standard and Mini, AcuTwist and Acutrak 2 Micro, Mini, Standard, 4.7, and 5.5 screws are Intended as a fixation device for small bones, bone fragments, and osteotomies. It is not intended for interference or soft tissue fixation.

Acutrak Plus and (4/5), (6/7) and Acutrak 2 (7.5) and Dual-Trak screws are intended for fusions, fractures, or osteotomies of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, and calcaneous.

The Acutrak Screw Systems are intended for use by surgeons with orthopedic training and knowledge of the indications and techniques required for fracture fixation. The device is to be implanted by the surgeon in a sterile operating room setting.

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.

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510(k) Summary

Prepared on: 2022-12-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Acumed LLC
Applicant Address	5885 NE Cornelius Pass Rd. Hillsboro OR 97124 United States
Applicant Contact Telephone	925-353-7073
Applicant Contact	Mr. Saleh Amirriyazi
Applicant Contact Email	saleh.Amirriyazi@acumed.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Acumed Acutrak System Acumed Acturak 2 System
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K930834	Acutrak Fixation System	HWC
K944330	Acutrak Plus Fixation System	HWC
K110658	APTUS Cannulated Compression Screws	HWC
K123890	Acumed Cannulated Screw System	HWC
K163303	OsteoMed ExtremiFix Mid and Large Screw System	HWC
K202680	OsteoMed ExtremiFix Mini & Small Cannulated Screw System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this Traditional 510(k) is to add the MR conditional safety information to the labeling and provide performance data for Acutrak and Acutrak 2 Screw Systems. The intended use, technological characteristics, function and operating principles and anatomical site for implantation of the devices remain unchanged. No modification has been made to the device material, sterilization, packaging, and the manufacturing processes of the currently marketed devices.

The Acutrak and Acutrak 2 Screw Systems - MR Conditional (subject devices) are being compared to the existing on market Acutrak and Acutrak 2 Screw Systems (predicate devices). Mechanical performance of Acutrak and Acutrak 2 screws were compared to other comparable on market screws (other predicates).

The Acumed Acutrak and Acutrak 2 Screws are designed to provide fixation of various fractures and osteotomies while they heal. These

systems offer screws in different diameters and lengths to suit different anatomical locations, patient size, and fracture patterns. All the screws are manufactured from Titanium alloy per ASTM F136, are single use and are provided both sterile and non-sterile.

Instruments supplied to aid in the screw insertion and removal and are supplied sterile and/or non-sterile and most are reusable. Sterilization trays provided to house non-sterile implants and instruments.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Acutrak Fusion, Standard and Mini, AcuTwist and Acutrak 2 Micro, Mini, Standard, 4.7, and 5.5 screws are Intended as a fixation device for small bones, bone fragments, and osteotomies. It is not intended for interference or soft tissue fixation.

Acutrak Plus and (4/5), (6/7) and Acutrak 2 (7.5) and Dual-Trak screws are intended for fusions, fractures, or osteotomies of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, and calcaneous.

The Acutrak Screw Systems are intended for use by surgeons with orthopedic training and knowledge of the indications and techniques required for fracture fixation. The device is to be implanted by the surgeon in a sterile operating room setting.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject devices, Acutrak and Acutrak 2 Screw Systems, have the same indications for use as their corresponding predicate devices. The basis of substantial equivalence for the subject devices are the similarities in intended use, material, technology, operating principle, anatomical site for implantation, performance and design.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics, operating principles and anatomical site for implantation of the subject devices remain unchanged. Both subject and predicate devices are bone screws intended for fracture fixation of bones appropriate for their sizes. The subject and predicate screws achieve their intended use through a variety of diameters and lengths of screw size offerings.
No modification has been made to the device material, sterilization, packaging, and the manufacturing processes of the currently marketed devices.
While some differences exist in the basic shape, design and technology; however, the performance evaluation demonstrates that the subject screws are equivalent to their predicate screws.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing to support MR Conditional labeling was conducted per FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014, and the standards listed below:

- Magnetically induced displacement force (ASTM F2052)
- Magnetically induced torque (ASTM F2213)
- Radiofrequency (RF) induced heating (ASTM F2182)
- MR image artifact (ASTM F2119) include assessments of magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts.
- Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (ASTM F2503)

Performance data demonstrate that the Acumed Acutrak and Acutrak 2 screws, when used in the MR environment using specified MR parameters and instructions, are not adversely affected by magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts.

Mechanical performance testing (Torsional Yield Strength, Insertion Torque, and Axial Pullout Force) was conducted on the subject screws per ASTM F543-17 (Standard Specification and Testing Methods for Metallic Medical Bone Screws) and all screws passed acceptance criteria and demonstrated substantially equivalent mechanical performance to their corresponding predicate screws.

Clinical testing was not necessary.

Based on the results of the nonclinical testing described above, it was concluded that the subject and predicate devices are substantially equivalent in performance specifically for the intended use, hence the subject devices were proven to be safe and effective for the indications.