June 9, 2023

Acumed LLC
Phillip Saddik
Regulatory Affairs Specialist
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K230744
Trade/Device Name: Acumed Acutrak 3 Headless Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 15, 2023
Received: March 17, 2023

Dear Mr. Phillip Saddik:

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.

510(k) Number *(if known)*
K230744

Device Name
Acutrak 3 Headless Compression Screws

Indications for Use *(Describe)*
Acutrak 3 Headless Compression Screw System screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. The screws are not intended for interference or soft tissue fixation.

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
K230744

Date prepared: May 16th 2023

I. Contact Details

Applicant Name: Acumed LLC
Applicant Address: 5885 NE Cornelius Pass Rd. Hillsboro OR 97124 United States
Applicant Contact Name: Mr. Philip Saddik
Applicant Telephone: 917-586-5641
Applicant Contact Email: Philip.saddik@acumed.net

II. Device Name

Device Trade Name: Acumed Acutrak 3 Headless Compression Screw System
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040
Product Code: HWC

III. Legally Marketed Primary Predicate Devices

Primary Predicate Device: OsteoMed ExtremiFix Mini & Small Cannulated Screws Screw System K202680
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040
Product Code: HWC

Predicate Device: OsteoMed ExtremiFix Mid & Large Screw System, K163303
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040
Product Code: HWC

Predicate Device: OsteoMed ExtremiFix Mid & Large Screw System, K063298
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040
Product Code: HWC

Predicate Device: Medartis Aptus SpeedTip Cannulated Compression Screw System, K110658
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040
Product Code: HWC

Reference Device: Acumed Acutrak/Acutrak 2 System, K221333
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040
Product Code: HWC

IV. Device Description Summary

Acutrak 3 Headless Compression Screw System is a set of screws and instruments that are provided in case and tray configurations when distributed non-sterile as well as sterile packaged product. The system is an extension of the core technology cleared for Acumed's Acutrak and Acutrak 2 Headless Compression Screw Systems, per K930834, K944330 and K221333.

Acutrak 3 Headless Compression Screw System screws are designed for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. The system provides 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.

The AT3 System screws are an extension of the Acutrak family with new lengths and the addition of a new smaller screw size. AT3 System screws include 4 sizes, which are referred to as Nano, Micro, Mini and Standard. The screw naming scheme is not to imply the presence of any additional features in the screws. Screws are intended for single patient use only. The AT3 System introduces a modified variable pitch screw design designed to accommodate various fracture patterns for which the AT3 System can be used.

Instruments supplied with the AT3 System are intended to aid in the screw insertion and removal. Instruments are supplied sterile and non-sterile, to be sterilized by the end users. System cases consisting of screw trays, instrument trays, caddies and lids are also provided to house non-sterile implants and instruments.

V. Intended Use/ Indications for Use

Acutrak 3 Headless Compression Screw System screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. The screws are not intended for interference or soft tissue fixation.

VI. Indications for Use Comparison

The subject devices, Acutrak 3 Headless Compression Screw System screws, have the same indications for use as the predicate devices.

VII. Technological Comparison

The technological characteristics, operating principles and anatomical site for implantation of the subject device is identical to the predicates.

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 the use of variety of sizes, in terms of diameters and lengths.

While some differences exist in the basic shape and design of the screws, the performance evaluation demonstrates that the subject devices are equivalent to the predicate devices.

VIII. Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-Clinical testing to support performance was conducted per FDA's Guidance, *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway Guidance for Industry and Food and Drug Administration Staff,* December 11, 2020, and *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment- Guidance for Industry and Food and Drug Administration Staff*, May 20, 2021.

Safety and Performance evaluation conducted for the subject devices:

- Torsional Yield Strength (ASTM F543 Annex A1)
- Driving Torque (ASTM F543 Annex 2)
- Axial Pullout Force (ASTM F543 Annex 3)
- Self-Tapping Performance (ASTM F543-17 Annex 4)
- Sterilization (ISO 17665-1)
- Sterilization (ISO 11137-1)
- Packaging (ISO 11607-1)
- Biocompatibility (ISO 10993-1)
- Screw Lifetime Verification Testing
- Self-Drilling Verification Testing
- Magnetically Induced Displacement Force (ASTM F2052)
- Magnetically Induced Torque (ASTM F2213)
- MR Image Artifact (ASTM F2119)
- MRI Safety Labelling (ASTM F2503)

Performance data demonstrate that the Acutrak 3 Headless Compression Screw System screws are equivalent to the designated predicate devices when used as intended.

Clinical testing was not necessary.

Based on the results of the non-clinical testing described above, it was concluded that the subject and predicate devices are substantially equivalent when used as intended. Therefore, the subject devices were proven to be safe and effective for the indications.