April 22, 2024

Acumed LLC
Anusha Gedala
Regulatory Affairs Specialist
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K233311
Trade/Device Name: Acumed Wrist Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 19, 2024
Received: March 20, 2024

Dear Anusha Gedala:

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.

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,

Shumaya Ali -S

Shumaya Ali, MPH
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)*

K233311

Device Name
Acumed Wrist Plating System

Indications for Use *(Describe)*
Acumed Wrist Plating System provides fixation for fractures, fusions, or osteotomies of the distal radius and ulna.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date prepared: April 15, 2024

I. Contact Details

Applicant Name: Acumed LLC
Applicant Address: 5885 NE Cornelius Pass Rd. Hillsboro OR 97124 United States
Applicant Contact Name: Ms. Anusha Gedala
Applicant Telephone: 503-207-1638
Applicant Contact Email: anusha.gedala@acumed.net

II. Device Name

Device Trade Name: Acumed Wrist Plating System
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3030
21 CFR 888.3040
Product Code: HRS, HWC

III. Legally Marketed Primary Predicate Devices

Primary Predicate Device: Congruent Bone Plate System, K012655
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Regulation Number: 21 CFR 888.3030
Product Code: HRS

Predicate Device: Congruent Bone Plate System – Acu-Loc 2 Plate, K120903 / K102998
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3030
21 CFR 888.3040
Product Code: HRS, HWC

Reference Device: Acumed Hand Plating System, K132769
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Regulation Number: 21 CFR 888.3030

Product Code: HRS, HWC

Reference Device: Frag-Loc System, K130986
Common Name: Washer, Bolt, Nut
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Regulation Number: 21 CFR 888.3030
Product Code: HTN, HWC

IV. Device Description Summary

Acumed Wrist Plating System is a set of plates, 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 Congruent Bone Plate Systems, per K012655, K120903 and K102998.

Acumed Wrist Plating System plates and screws are designed to provide fixation for fractures, fusions, or osteotomies of the distal radius and ulna. The system provides plates and screws in different diameters and lengths to suit different anatomical locations, patient size, and fracture patterns. All the plates and screws are manufactured from titanium alloy per ASTM F136 and pure titanium per ASTM F67, are single use and are provided both sterile and non-sterile.

The Acumed Wrist Plating System plates and screws are an extension of the Congruent Bone Plate family with new lengths and the addition of new size plates and screws. Plates and screws are intended for single patient use only.

Instruments supplied with the Acumed Wrist Plating 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

The Acumed Wrist Plating System provides fixation for fractures, fusions, or osteotomies of the distal radius and ulna.

VI. Indications for Use Comparison

The subject device system, Acumed Wrist Plating System includes a subset of the indications for use of the primary predicate device, Congruent Bone Plate System (K012665).

VII. Technological Comparison

The operating principles and anatomical site for implantation of the subject device are identical to the predicate devices. Both subject and predicate devices are bone plates and screws intended to provide fixation for fractures, fusions and osteotomies. There are some differences in basic shape, design, and size between the subject and predicate.

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

Non-Clinical testing to support performance was conducted per FDA's Guidance:

Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway Guidance for Industry and Food and Drug Administration Staff, April 11, 2022

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

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:

- Safety and Performance evaluation conducted for the subject devices (ASTM F382-17)
- 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 demonstrates that the Acumed Wrist Plating System plates and 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.