July 14, 2025

Acumed LLC
Marina Bull
Regulatory Affairs Specialist
5885 NE Cornelius Pass Rd
Hillsboro, Oregon 97124

Re: K251132
Trade/Device Name: The Acumed Wrist Fixation System - Plates;
The Acumed Wrist Fixation System - Screws
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: June 13, 2025
Received: June 13, 2025

Dear Ms. Bull:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.,
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251132

Please provide the device trade name(s).

The Acumed Wrist Fixation System - Plates
The Acumed Wrist Fixation System - Screws

Please provide your Indications for Use below.

The Indications for Use for The Acumed Wrist Fixation System / Plates, is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna.

The Indications for Use for The Acumed Wrist Fixation System/ Screws, is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251132

510(k) Summary

Prepared on: 2025-07-11

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	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	The Acumed Wrist Fixation System - Plates; The Acumed Wrist Fixation System - Screws
Common Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Name	Plate, Fixation, Bone Screw, Fixation, Bone,
Regulation Number	888.3030, 888.3040
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233311	The Acumed Wrist Plating System	HRS
K131764	Acumed Wrist Spanning Plate	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Acumed Wrist Fixation System is a new system designed for distal radius and ulna fracture fixation. The system is comprised of plates, screws, and instruments designed to aid in implantation. The intended use of the Acumed Wrist Fixation System is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna. The implants are manufactured from Titanium Alloy per ASTM F136-13(2021)e1 and Cobalt Chrome per ASTM F1537-20. The implants are provided sterile and non-sterile and are for single use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Indications for Use for The Acumed Wrist Fixation System / Plates, is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna.

The Indications for Use for The Acumed Wrist Fixation System/ Screws, is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Acumed Wrist Fixation System has been compared to the predicate devices, The Acumed Wrist Plating System (K233311) and the

Acumed Wrist Spanning Plate (K131764) within this 510(k) submission. The basis of substantial equivalence for the subject device to the predicate devices are their similarities in intended use, material technology, operating principles, anatomical site for implantation, performance and design. The analysis of differences do not constitute a new intended use, and the information included within the submission demonstrated that the subject device is substantially equivalent to the predicate devices (The Acumed Wrist Plating System K233311 and The Acumed Wrist Spanning Plate K131764) and does not raise different questions of safety or effectiveness.

The Acumed Wrist Fixation System has the same Intended Use/Indications for Use as The Acumed Wrist Plating System (K233331) and The Acumed Wrist Spanning Plate (K131764).

Technological Comparison 21 CFR 807.92(a)(6)

The Acumed Wrist Fixation System, has been compared to the predicate devices, The Acumed Wrist Plating System (K233311) and The Acumed Wrist Spanning Plate (K131764) within the 510(k) submission. The basis of substantial equivalence for the subject device to the predicate devices is their similarities in the intended use, material technology, operating principles, anatomical site for implantation, performance and design. The analysis of differences does not constitute a new intended use, and the information included within the submission demonstrated that the subject device is substantially equivalent to the predicate devices, and does not raise different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Volar Distal Radius (VDR) Plates and the Wrist Spanning Plates in The Acumed Wrist Fixation System were compared to the Predicate Device, The Acumed Wrist Plating System (K233311) and The Acumed Wrist Spanning Plate (K131764), per ASTM F382-24, Standard Specification and Test Method for Metallic Bone Plates issued on August 15, 2024. The mechanical performance for the subject plates were compared to the predicate plates for static and simulated dynamic 4-point bending testing that was conducted based on a validated CAD model.

Torsional strength and driving torque testing of the subject screws was conducted according to ASTM F543-23, Standard Specification and Test Methods for Metallic Medical Bone Screws.

Theoretical axial pullout strength calculation of the subject screws according to F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws.

Single cycle bend testing of the subject pegs according to ASTM F384-17, Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.

Corrosion testing was conducted according to ASTM F3044-20 Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants.

Magnetically induced force, torque, radio frequency induced heating, and image artifact evaluations 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 F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment, ASTM F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, and ASTM F2119 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, ASTM F2182.

Clinical testing was not required to support substantial equivalence (Not Applicable).

The Acumed Wrist Fixation System (Subject Device) has undergone testing in accordance with the FDA issued Guidance Documents:
1. Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway issued-on April 11, 2022.
2. Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway issued on November 22, 2024.
The evaluation performed against the Safety and Performance based Pathway Guidance Documents have all generated passing results, deeming this system substantially equivalent to The Acumed Wrist Plating System (K233311) and The Acumed Wrist Spanning Plate (K131764).