June 24, 2025

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

Re: K251296
Trade/Device Name: The Acumed Wrist Fixation 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, HTN

Dear Marina Bull:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 18, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the correct version of the 510(k) Summary for K251296.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Christopher Ferreira, M.S., OHT6: Office of Orthopedic Devices, 301-796-9350, Christopher.Ferreira@fda.hhs.gov.

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

June 18, 2025

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

Re: K251296
Trade/Device Name: The Acumed Wrist Fixation 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, HTN,
Dated: April 25, 2025
Received: April 25, 2025

Dear Marina 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, MS
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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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.	K251296

Please provide the device trade name(s).

The Acumed Wrist Fixation System

Please provide your Indications for Use below.

The Indications for Use for The Acumed Wrist Fixation System 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) #: K251296

510(k) Summary

Prepared on: 2025-04-25

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
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC, HTN

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

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 Acumed Wrist Fixation System will be 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 Pure Titanium (UNS R50400 (CPTi GRADE 2) PER ASTM-F67-13(2017)) and Titanium Alloy (TI-6AI-4V PER ASTM F136-13(2021) e1). 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 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 device, The Acumed Wrist Plating System 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 do not constitute a new intended use, and the information included within the submission demonstrated that the subject device is comparable to the predicate device 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.

Technological Comparison 21 CFR 807.92(a)(6)

The Subject Device has the same technological characteristics as the Predicate Device. The technological characteristics, operating principles, and anatomical site for implantation of the subject device is identical to that of the predicate device, which is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna. The subject device, predicate device and reference device systems are used to fixate bone, resulting in rigid fixation.

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

The Volar Distal Radius Extension Plates, Volar Distal Radius (VDR) Extension Plate Link Screw, and Volar Distal Radius (VDR) Plates (submitted under K251132) in The Acumed Wrist Fixation System were compared to the Predicate Device, The Acumed Wrist Plating System (K233311) 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 dynamic 4-point bending performance.

The Adjunct Plates in The Acumed Wrist Fixation System were compared to the Predicate Device, The Acumed Wrist Plating System (K233311) per ASTM F3437-23, Standard Test Methods for Metallic Bone Plates Used in Small Bone Fracture Fixation issued on April 07, 2023. The mechanical performance for the subject plates were compared to the predicate plates for static cantilever bending performance.
The Frag-Loc Screw & Sleeve in The Acumed Wrist Fixation System were compared to the Predicate Device, The Acumed Wrist Plating System (K233311) per ASTM F1264-16, Standard Specification and Test Methods for Intramedullary Fixation Devices issued on September 02, 2024. The mechanical performance for the subject screw and sleeve were compared to the predicate screw and sleeve for static 3-point bending performance.

The Buttress Plates (Short & Long) in The Acumed Wrist Fixation System were compared to the 6mm Washer in the Reference Device, OsteoMed ExtremiLOCK Wrist Plating System (K161041). The contact area of the Buttress Plates (Short & Long), which are 6mm x 8mm & 6mm x 15.5mm respectively, are greater than that of the Reference Device. Since a larger contact area provides greater resistance to pull through, mechanical testing was excluded for these devices.
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) was evaluated against The Acumed Wrist Plating System (K233311 Predicate Device) & OsteoMed ExtremiLOCK Wrist Plating System (K152145 Reference Device) for substantial equivalence. Based on the results of the nonclinical bench testing described above, it was concluded that the Subject and Predicate Devices are equivalent in performance for the intended use, therefore the Subject Device was proven to be safe and effective for the indication.