August 21, 2025

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

Re: K252356
Trade/Device Name: The Acumed Wrist Fixation System - 2.4mm 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: July 29, 2025
Received: July 29, 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, 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 - 2.4mm Screws

Please provide your Indications for Use below.

The 2.4mm Non-Locking (NL) Hexalobe Screws are intended to be used in conjunction with The Acumed Wrist Fixation System, which consists of plates, screws, and instruments designed to aid in implantation. The intended use of the 2.4mm NL Hexalobe Screw is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna when used in conjunction with The Acumed Wrist Fixation System.

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) #: K252356

510(k) Summary

Prepared on: 2025-07-29

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 - 2.4mm Screws
Common Name	Screw, Plate, Fixation, Bone
Classification Name	Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
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
K251132	The Acumed Wrist Fixation System	HRS, HWC

Device Description Summary

21 CFR 807.92(a)(4)

The 2.4mm Non-Locking (NL) Hexalobe Screws are intended to be used in conjunction with The Acumed Wrist Fixation System, which consists of plates, screws, and instruments designed to aid in implantation. The intended use of the 2.4mm NL Hexalobe Screw is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna when used in conjunction with The Acumed Wrist Fixation System. The implant is manufactured from Titanium Alloy per ASTM F136-13(2021)e1. The implant is provided sterile and non-sterile and is for single use only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The 2.4mm Non-Locking (NL) Hexalobe Screws are intended to be used in conjunction with The Acumed Wrist Fixation System, which consists of plates, screws, and instruments designed to aid in implantation. The intended use of the 2.4mm NL Hexalobe Screw is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna when used in conjunction with The Acumed Wrist Fixation System.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The primary method of determining Substantial Equivalence is the standard Performance Based Pathway. The following Guidance Documents were used to determine Substantial Equivalence.

1. Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway issued on November 22, 2024.

The basis of substantial equivalence between the Subject Device and the Predicate Devices is their similarities in intended use, material,

technology, operating principles, anatomical site for implantation, performance and design. The analysis between the Subject Devices and Predicate Devices supports substantial equivalence as the differences do not constitute a new intended use and do not raise additional questions of safety and effectiveness.
The proposed indications for use are: The 2.4mm Non-Locking (NL) Hexalobe Screws are intended to be used in conjunction with The Acumed Wrist Fixation System, which consists of plates, screws, and instruments designed to aid in implantation. The intended use of the 2.4mm NL Hexalobe Screw is to provide fixation of fractures, fusions, osteotomies, and nonunions of the distal radius and ulna when used in conjunction with The Acumed Wrist Fixation System.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject Device has the same technological characteristics as the Predicate Device except for difference in screw head design. 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 when used in conjunction with The Acumed Wrist Fixation System, per ASTM F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The 2.4mm Non-Locking Hexalobe Screws were compared to the Predicate Device, The 2.4mm Non-Locking Hexalobe Screw cleared under K251132, As part of The Acumed Wrist Fixation System, per ASTM F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws.

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 ASTM F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws.

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 2182 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.

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

The 2.4mm Non-Locking Hexalobe Screws (Subject Device) have undergone testing in accordance with the FDA issued Guidance Document:
1. 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 Document have generated passing results, deeming the 2.4mm Non-Locking Hexalobe Screws substantially equivalent to the Predicate Device, The 2.4mm Non-Locking Hexalobe Screws as Part of The Acumed Wrist Fixation System (K251132).