February 12, 2026

Met One Technologies, LLC
Liberato Aguilar
COO
4519 Osborne Drive
Suite C
El Paso, Texas 79922

Re: K251732
Trade/Device Name: Wrist Fracture 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: January 15, 2026
Received: January 15, 2026

Dear Liberato Aguilar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.	K251732

Please provide the device trade name(s).

Wrist Fracture System

Please provide your Indications for Use below.

The Wrist Fracture System Distal Radius Plate is indicated for fixation of fractures, osteotomies, and non-unions of the distal radius.

The Wrist Fracture System Dorsal Bridge Plate is indicated for fixation of fractures, osteotomies, and non-unions of the radius.

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) #: K251732

510(k) Summary

Prepared on: 2026-01-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Met One Technologies, LLC
Applicant Address	4519 Osborne Drive Suite C El Paso TX 79922 United States
Applicant Contact Telephone	915-373-3855
Applicant Contact	Mr. Evan Carbonell
Applicant Contact Email	evan@met1tech.com
Correspondent Name	Met One Technologies, LLC
Correspondent Address	4519 Osborne Drive Suite C El Paso TX 79922 United States
Correspondent Contact Telephone	915-892-6044
Correspondent Contact	Mr. Liberato Aguilar
Correspondent Contact Email	libe@met1tech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Wrist Fracture System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, 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
K172170	APTUS® Wrist 2.5 System	HRS
K222637	Trimed Wrist Fixation System 3	HRS
K233154	SkyOPS™ Orthopedic Plate System	HRS
K233311	Acumed Wrist Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Met One Technologies Wrist Fracture System is an implant system for the repair of radius fractures. Included in the system are titanium fracture plates, titanium bone screws, k-wires, and surgical instrumentation.

Distal radius plates are intended for fixation of fractures, osteotomies and non-unions of the distal radius. Various widths and lengths of distal radius plates are available to accommodate differences in patient anatomy. The dorsal bridge plate is intended for fixation of fractures, osteotomies and non-unions of the radius. One size of dorsal bridge plate is available. All plates are offered in multiple titanium grades and production processes which includes grade 23 titanium (Ti-6Al-4V ELI) per ASTM F136, grade 4 titanium (CP Ti) per ASTM F67, additively manufactured grade 23 titanium (Ti-6Al-4V ELI) per ASTM F3001, and additively manufactured grade 1 titanium (CP Ti). Each plate is designed with pre-determined hole angles and incorporates a self-locking mechanism to resist movement of the screw relative to the plate.

Screws are available in two diameters (2.4 mm and 3.0 mm) and in a variety of lengths to accommodate differences in patient anatomy. All screws are manufactured from grade 23 titanium (Ti-6Al-4V ELI) per ASTM F136. The 2.4 mm screws are designed to allow a 30° cone of variable angle locking when used with fracture plates. The 3.0 mm screws are intended to be inserted orthogonal to the bone plate in predetermined holes where they self-lock with the fracture plate.

K-wires are available in 1.1mm diameter and are used for temporary fixation or permanent implantation in specifically designed holes in fracture plates. K-wires are manufactured from 316L stainless steel per ASTM F138 or grade 23 titanium (Ti-6Al-4V ELI) per ASTM F136.

Instruments are provided for the preparation, implantation, and removal of implants. All instruments are reusable.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Wrist Fracture System Distal Radius Plate is indicated for fixation of fractures, osteotomies, and non-unions of the distal radius.

The Wrist Fracture System Dorsal Bridge Plate is indicated for fixation of fractures, osteotomies, and non-unions of the radius.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Wrist Fracture System has identical or similar indications for use as the primary and additional predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The Wrist Fracture System has similar technological characteristics, surgical approach, materials, range of sizes, design, and principles of operation as the predicate devices. Any differences in technological characteristics do not raise different questions of safety or effectiveness. Performance testing demonstrates the device has mechanical performance substantially equivalent to that of the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical testing was performed to demonstrate substantial equivalence using ASTM F382 Static Four-point Bend Testing, ASTM F382 Dynamic Four-point Bend Testing, ASTM F543 Torsional Properties, and ASTM F543 Driving/Removal Torque.

Not Applicable

The results of the mechanical testing showed that the worst-case constructs were substantially equivalent to legally marketed devices.