November 12, 2025

Intrauma S.p.A
% Stefano Pullega
QA&RA Director and Person Responsible for Regulatory Compliance
Via Meucci, 5
Bruino (TO), 10090 Italy

Re: K252959
Trade/Device Name: WRISTAR MultiAx Distal Radius Kit
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: September 16, 2025
Received: September 16, 2025

Dear Stefano Pullega:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K252959

Device Name

WRISTAR MultiAx Distal Radius Kit

Indications for Use *(Describe)*

The Wristar MultiAx Distal Radius Kit is indicated for:
- Fixation of complex intra- and extra-articular fractures of the distal radius
- osteotomies of the distal radius

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

| | |
|---|---|
| **Device Trade Name:** | WRISTAR MultiAx Distal Radius Kit |
| **Manufacturer:** | Intrauma S.p.A.<br>Via Meucci, 5<br>Bruino (TO) Italy 10090 |
| **Primary Contact:** | Stefano Pullega<br>QA&RA Director and Person Responsible for Regulatory Compliance<br>Intrauma S.p.A.<br>Via Meucci, 5<br>Bruino (TO) Italy 10090<br>Office: +39.011.9539496<br>Mobile: +39. 344.348851<br>stefano.pullega@intrauma.com |
| **Prepared by:** | MCRA, LLC<br>803 7th Street, NW, 3rd Floor<br>Washington, DC 20001<br>Office: 202.552.5800 |
| **Date Prepared:** | September 16, 2025 |
| **Classifications:** | 21 CFR 888.3030 - Single/Multiple Component Metallic Bone Fixation Appliances And Accessories |
| **Class:** | II |
| **Product Codes:** | HRS - Plate, Fixation, Bone<br>HWC - Screw, Fixation, Bone |
| **Primary Predicate:** | Synthes 2.4mm VA-LCP Two-Column Volar Distal Radius Plate (K083694) |
| **Additional Predicate:** | Synthes 2.4mm Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System (K071184) |

**Indications For Use:**

The Wristar MultiAx Distal Radius Kit is indicated for:

- Fixation of complex intra- and extra-articular fractures of the distal radius
- osteotomies of the distal radius

**Device Description:**
The WRISTAR MultiAx Distal Radius Sterile Kit is indicated for both intra-articular and extra-articular fractures of the distal radius (2R3-A2 and 2R3-A3, 2R3-B/C) and for distal radius osteotomies. The system is comprised of various plates and screws which allow it to be customized to a patient's anatomy and fracture pattern. The plate is secured in place via MultiAxial and cortical screws.

The WRISTAR MultiAx Distal Radius Volar Plate is available in various lengths to accommodate patient anatomy and fracture type of the malleolus bone. The plate is provided either with threaded holes or tapered holes. The head of the plate has a shape and contour that provides bone support and a low profile that minimizes the potential for soft tissue irritation. Screws are available in two designs: cortical and MultiAx.

**Predicate Device:**
Intrauma S.p.A. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, WRISTAR MultiAx Distal Radius Sterile Kit is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

- Primary Predicate: Synthes 2.4mm VA-LCP Two-Column Volar Distal Radius Plate (K083694)

- Reference Device: Synthes 2.4mm Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System (K071184)

**Performance Testing Summary:**
Static 4-point bending tests were performed in order to measure the bending stiffness, the bending structural stiffness and the bending strength of a bone plate using a 4-Point Bending test according to ASTM F382-17 Annex A1. Torsional, insertion / removal torque, pull-out, and self-tapping testing were performed according to ASTM F543-17 on the worst case MultiAx screw. The testing demonstrated conformance with FDA's guidance Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway.

**Substantial Equivalence:**
The WRISTAR MultiAx Distal Radius Sterile Kit is substantially equivalent to the predicate devices with respect to indications, design, function, and performance.

**Conclusion:**
The subject and predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The WRISTAR MultiAx Distal Radius Sterile Kit is as safe, as effective, and performs as well as the predicate devices.