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.

510(k) Number *(if known)*
K231684

Device Name
Quick - Radius Disposable Set

Indications for Use *(Describe)*
Quick - Radius Disposable Set is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand and wrist. The use of locking plate and screw systems is suited for treatment of fractures in osteopenic bone.

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.

510(k) Summary
K231684

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter:

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Date prepared: January 11, 2024

II. Device Name:

Trade/Device Name:	Quick - Radius Disposable Set
Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Regulation Number:	21 CFR 888.3030 (Primary) 21 CFR 888.3040
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories. (Primary) Smooth or threaded metallic bone fixation fastener.
Regulatory Class:	II
Product Codes:	HRS (Primary) HWC

III. Predicate Devices:

Legally marketed devices to which we are claiming "Substantial Equivalence" are the following:

Mini and Micro Fragments Reconstruction System - GMReis (K182718) (Primary predicate device).

Synthes (USA) 2.4mim VA-LCP Two-Column Narrow Volar Distal Radius Plates - Synthes (USA) (K092556) (Reference device).

EXPERT - Joint Fixation System - GMReis (K200332) (Reference device).

IV. Device Description:

Quick - Radius Disposable Set are plate and instruments kit, for osteosynthesis procedures of the distal radius, in sterile condition, single use and disposable instruments after use. This sterile set must be used with 2.4mm screws, also sterile and individually packaged. The surgeon selects the best combination of plate size, left or right and screw designs and quantities, as needed. Single use and sterile templates are available, individually packed, for determining the size of the plate to be used. Also, as an option, individually packed plates, instruments only kit, and instruments with plates and screws kit, are available in sterile condition.

The plates and screws are produced with Titanium Alloy, according with standard ASTM F136, and the instruments are made of Stainless Steel, according with standard ASTM F899.

V. Statement of Indications for Use of the Device:

Quick - Radius Disposable Set is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand and wrist. The use of locking plate and screw systems is suited for treatment of fractures in osteopenic bone.

VI. Comparison of Technological Characteristics with The Predicate Device:

The proposed device is a line extension to the predicate device with new presentation forms. The proposed and predicate devices have the same basic design, intended use and biocompatibility profile. Difference between the proposed device and the predicate includes addition of a presentation form in a sterile condition. The proposed Quick - Radius Disposable Set is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise new or different questions concerning safety or effectiveness.

VII. Performance Data:

The subject Quick - Radius Disposable Set components possess the same technological characteristics as the predicate devices. These include:

- performance;
- shape and dimensions;
- material and manufacturing;
- sizes;
- biocompatibility and
- device usage.

The sterilization method is ethylene oxide exposure. The EO sterilization has been validated to a sterility assurance level (SAL) of 10^{-6}, according to ISO 11135 - Sterilization of health care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices.

VIII. Conclusions:

The Quick - Radius Disposable Set is substantially equivalent to the predicate device in which the basic design features and intended use are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise and

different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, GMReis has determined that the proposed device is substantially equivalent to the currently marketed predicate device.

January 12, 2024

GM Dos Reis Industria e Comercio Ltda
Guilherme Esteves Pontes
Regulatory Affairs Analyst
Avenida Pierre Simon de La Place 600
Campinas, SP 13069-320
Brazil

Re: K231684
Trade/Device Name: Quick - Radius Disposable Set
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: May 18, 2023
Received: June 9, 2023

Dear Guilherme Esteves Pontes:

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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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