March 17, 2026

GM Dos Reis Industria e Comercio Ltda.
Guilherme Esteves Pontes
Senior Regulatory Affairs Specialist
Avenida Pierre Simon De La Place, 600
Campinas, SP 13069320
Brazil

Re: K260390
Trade/Device Name: Super Upper Limbs Versalock Plating 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: February 4, 2026
Received: February 6, 2026

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 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. | K260390 |

Please provide the device trade name(s).

Super Upper Limbs Versalock Plating System

Please provide your Indications for Use below.

The Super Upper Limbs Versalock Plating System is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand, wrist and forearm. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

## Section 5 - 510(k) Summary

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

**I. Submitter:**

GM Dos Reis Industria e Comercio Ltda
Avenida Pierre Simon de La Place 600
Campinas, São Paulo, Brazil 13069-320
Guilherme Esteves Pontes, Senior Regulatory Affairs Analyst
Telephone: +55 (19) 3765-9900
Email: qualidade4@gmreis.com.br
Date prepared: February 04, 2026

**II. Device Name:**

| | |
|---|---|
| Trade Name: | Super Upper Limbs Versalock Plating System |
| Common Name: | Plate, fixation, bone; Screw, fixation, bone |
| Classification Name: | Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener |
| Device Class: | II |
| Product Codes: | HRS / HWC |
| Regulation Number: | 21 CFR 888.3030 / 21 CFR 888.3040 |

**III. Predicate Devices:**

Legally marketed device to which we are claiming “Substantial Equivalence” are the following:
Mini and Micro Fragments Reconstruction System - GMReis (K182718) (Primary Predicate Device)
Versalock Mini and Micro Plating System (K242596) (Additional Predicate Device)
APTUS® Wrist 2.5 System (K142906) (Additional Predicate Device)
Fracture Plates (K123241) (Additional Predicate Device)
APTUS® Wrist 2.5 System (K172170) (Additional Predicate Device)
Mini and Micro Fragments Reconstruction System-Neofix (K142419) (Additional Predicate Device)
Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684) (Additional Predicate Device)

APTUS® Ulna Shortening 2.5 (K141232) (Additional Predicate Device)
Small Fragment Plates and Screws (K951302) (Additional Predicate Device)
Versalock Rib and Sternum Plates System (K232829) (Reference Device)

**IV. Device Description:**

The Super Upper Limbs Versalock Plating System consists of plates and screws in a variety of designs and sizes that are commonly used in trauma and reconstructive surgery. The bone plates and screws are made from commercial titanium alloy and pure titanium. The plates range in thickness from 0.6 to 4.0 mm, and the screws range in diameter from 2.0 to 3.5 mm.

Super Upper Limbs Versalock Plating System implants are manufactured with the following raw materials:

- Titanium Alloy Ti6Al4V according to ASTM F136
- Pure Titanium according to ASTM F67

**V. Statement of Indications for Use of the Device:**

The Super Upper Limbs Versalock Plating System is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand, wrist and forearm. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone.

**VI. Comparison of Technological Characteristics with The Predicate Devices:**

The subject device is substantially equivalent in indications and design principles to the following predicate devices:

K182718 - Mini and Micro Fragments Reconstruction System - GMReis
K242596 - Versalock Mini and Micro Plating System
K142906 - APTUS® Wrist 2.5 System
K123241 - Fracture Plates
K172170 - APTUS® Wrist 2.5 System
K142419 - Mini and Micro Fragments Reconstruction System-Neofix
K000684 - Synthes Small Fragment Dynamic Compression Locking (DCL) System
K141232 - APTUS® Ulna Shortening 2.5
K951302 - Small Fragment Plates and Screws
K232829 - Versalock Rib and Sternum Plates System

The subject and predicate device have equivalent intended use and equivalent technological characteristics. Both devices are manufactured from identical materials and share equivalent design characteristics as well as physical dimensions. Any difference in technological characteristics do not raise new issues of safety or efficacy. The performance of the subject device was demonstrated through mechanical testing according to standards and predicate comparison. No clinical data were included in this submission.

**VII. Performance Data:**

Mechanical testing was performed according to ASTM F382 and ASTM F543 and all tests confirmed that the product met the predetermined acceptance criteria.

**VIII. Conclusions:**

As was established in this submission, the subject Super Upper Limbs Versalock Plating System are equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have the same technological characteristics, intended use, indications for use, material composition, anatomical region, multiple sizes, and basic design features compared to its predicate devices. Any differences between the subject and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. Based on the information provided, GMReis has determined that the proposed device is substantially equivalent to the predicate device.