November 21, 2024

GM Dos Reis Industria e Comercio Ltda
Guilherme Esteves Pontes
Regulatory Affairs Analyst
Avenida Pierre Simon de La Place, 600
Campinas, 13069320
Brazil

Re: K242998
Trade/Device Name: GMReis Ankle 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: September 26, 2024
Received: September 26, 2024

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.

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, MS
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)*

K242998

Device Name

GMReis Ankle Plating System

Indications for Use *(Describe)*

GMReis Ankle Plating System are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle.

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.

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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, Regulatory Affairs Analyst
Phone: +55 (19) 3765-9900
Email: qualidade4@gmreis.com.br
Date prepared: September 26, 2024

II. Device Name:

Trade Name:	GMReis Ankle Plating System
Common Name:	Plate, fixation, bone; Screw, fixation, bone
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Device Class:	II
Product Codes:	HRS; HWC
Regulation Number:	21 CFR 888.3030; 21 CFR 888.3040

III. Predicate Devices:

Legally marketed devices to which we are claiming “Substantial Equivalence” are the following:
Fracture Plates (K123241) (Primary predicate device);
Mini and Micro Fragments Reconstruction System - GMReis (K182718) (Reference device);

IV. Device Description:

GMReis Ankle 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 titanium alloy. The plates range in thickness from 1.8 to 3.6 mm, and the screws range in diameter from 2.7 to 3.5 mm. They are available on different sizes and shapes, according to the implantation site and the extension of the fracture.

GMReis Ankle Plating System are for single use. The devices are provided non-sterile and must being properly cleaned and sterilized before use, according to the recommendations provided in the Instructions for Use.

V. Statement of Indications for Use of the Device:

GMReis Ankle Plating System are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle.

VI. Comparison of Technological Characteristics with The Predicate Device:

The subject, the predicate and the reference devices have the same basic design and intended use. Both are packed using the same materials and are to be sterilized by the same methods. All of the subject device final finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the previously cleared reference device in K182718, and therefore are substantially equivalent to the predicates with regard to materials and biocompatibility.

VII. Performance Data:

The performance of the subject devices are demonstrated through mechanical testing of plates and screws according to ASTM F382 and ASTM F543, respectively. Based on submitted testing data, the subject device is equivalent to the predicate devices.

VIII. Conclusions:

The GMReis Ankle Plating System has the basic design features and intended use as the predicate. Any differences between them are considered minor and do not raise questions concerning safety or effectiveness. Based on the information provided, GMReis has determined that the proposed device is substantially equivalent to the predicate device.

GM dos Reis Industria e Comercio Ltda.
Pierre Simon de Laplace Ave., 600, Block 3F9677
Techno Park, Campinas, SP, Brazil, Zip Code 13069320
Phone: +551937659900, Email: gmreis@gmreis.com.br
Website: www.gmreis.com.br