June 12, 2025

GM Dos Reis Industria e Comercio
Guilherme Esteves Pontes
Senior Regulatory Affairs Analyst
Avenida Pierre Simon de LaPlace, 600
Campinas, SP 13069320
Brazil

Re: K250559
Trade/Device Name: GMReis Fibula Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 25, 2025
Received: May 27, 2025

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.06.12 17:03:04 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.	K250559

Please provide the device trade name(s).

GMReis Fibula Nail System

Please provide your Indications for Use below.

The GMReis Fibula Nail System is intended for fixation of fractures and osteotomies of the fibula.

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)

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:

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Campinas, São Paulo, Brazil 13069-320
Guilherme Esteves Pontes, Regulatory Affairs Analyst
Phone: +55 (19) 3765-9900
Email: qualidade4@gmreis.com.br
Date prepared: February 25, 2025

II. Device Name:

Trade Name:	GMReis Fibula Nail System
Common Name:	Rod, fixation, intramedullary and accessories
Classification Name:	Intramedullary fixation rod
Device Class:	II
Product Codes:	HSB
Regulation Number:	21 CFR 888.3020

III. Predicate Devices:

Acumed Small Bone IM Nail System (K143276) (Primary predicate device);
Acumed Congruent Bone Plate System (K102998) (Reference device);
Versalock Periprosthetic Femur Plates System (K201728) (Reference device).
Suture Anchors - HTA Headless Titanium Anchor and ZIP Anchors (K223114) (Reference device).
Versalock Rib and Sternum Plates System (K232829) (Reference device).

IV. Device Description:

The GMReis Fibula Nail System is a system of locked intramedullary nails for osteosynthesis of fibular fractures. It has multiple lengths (110mm to 180mm) and diameters (3.0mm and 3.6mm). The arrangement of the holes in the intramedullary nails allows the surgeon to block the implant in different planes. The screws

have a specific profile that reduces the risk of skin prominence and have threaded locking in the nail holes. GMReis Fibula Nail System are manufactured with titanium alloy, are for single use and the devices are provided non-sterile and must be properly cleaned and sterilized before use, according to the recommendations provided in the Instructions for Use.

V. Indications for Use:

The GMReis Fibula Nail System is intended for fixation of fractures and osteotomies of the fibula.

VI. Comparison of Technological Characteristics with The Predicate Device:

The subject and the predicate device have the same basic design and intended use. Both are manufactured and 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 devices in K201728, K223114 and K232829 and therefore are substantially equivalent with regard to materials, packaging and biocompatibility. The minor differences between the subject and predicate devices are regarding the length and diameter of the intramedullary nails. The predicate device has longer nails, as well as both smaller and larger diameters of nails compared to the subject device. Predicate has the option of stainless steel products, in addition to titanium, while the subject device is only in titanium. These minor differences do not affect the safety and effectiveness of the subject device and can be determined substantially equivalent.

VII. Performance Data:

The performance of the subject devices are demonstrated through mechanical testing according to ASTM F1264 and ASTM F543, respectively. Based on submitted testing data, the subject device is equivalent to the predicate device.

VIII. Conclusions:

The subject devices has the same design features and intended use as the predicate. Any differences between them 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.

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