March 8, 2021

GM dos Reis Industria e Comercio Ltda
% Janine Treter
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Alem Saadi, 855/2402
Ribeirao Preto, Sao Paulo 14096-570
Brazil

Re: K201728
Trade/Device Name: Versalock Periprosthetic Femur Plates System-GMReis
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, JDP, HWC, JDQ
Dated: January 22, 2021
Received: January 29, 2021

Dear Janine Treter:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201728

Device Name
Versalock Periprosthetic Femur Plates System - GMReis

Indications for Use *(Describe)*

The Versalock Periprosthetic Femur Plates System – GMReis is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the femur, including:

- Periprosthetic fractures
- Comminuted fractures
- Supracondylar fractures
- Trochanteric fractures
- Fractures in normal and osteopenic bone
- Non-unions and Malunions.

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.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor/Manufacturer Name	GM dos Reis Indústria e Comércio Ltda Avenida Pierre Simon de La Place 600 Campinas, São Paulo, Brazil 13069-320 Telephone: +55 (19) 3765-9900 Contact person: Paula Oliveira, Quality Manager
Submission contact	Graziela Brum Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: graziela@rapassarini.com.br Telephone +55 (47) 3804 0075
Preparer	Janine Treter and Graziela Brum Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: graziela@rapassarini.com.br Telephone +55 (47) 3804 0075
Date Prepared	05/march/2021

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Versalock Periprosthetic Femur Plates System - GMReis
Common Name	Plate, Fixation, Bone; Condylar Plate Fixation Implant; Screw, Fixation, Bone; Cerclage, Fixation.
Classification Name	Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener; Bone fixation cerclage.
Product Code	HRS, JDP, HWC, JDQ
Classification Regulation	21 CFR 888.3030, 21 CFR 888.3040, 21 CFR 888.3010
Review Panel	Orthopedic

PREDICATE DEVICE INFORMATION

Primary Predicate Device	**K120772** - NCB Periprosthetic Trochanter Plates and Screws and NCB Cable Button for NCB Polyaxial Locking Plate - Zimmer, GmbH
Reference Devices	**K082527**- Zimmer® Universal Locking System: 3.5 mm Locking Plates and Screw (Tivanium® Ti-6A1-4V Alloy, CP Grade Titanium) - Zimmer, Inc. **K110354**- Synthes 4.5mm VA-LCP Curved Condylar Plate System - Synthes (USA) **K151907** - Cable-Ready® Cable Grip System: Cable-Ready® GTR System, Cable-Ready® 1.8mm - Zimmer, Inc. **K081759** - NCB® Polyaxial Locking Plate System, Proximal Humeral Plates and Zimmer® Universal Locking System; 3.5mm Tivanium® Ti-6A1-4V Alloy Locking Screws - Zimmer, GmbH **K061211**- NCB® Plating System - Zimmer, GmbH **K151716-** Cable-Ready® Cable Grip System: Cable-Ready® Bone Plate System - Zimmer, Inc. **K100111**- NCB® Periprosthetic Femur Polyaxial Locking Plate System - Zimmer, Inc. **K161616**- DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws, DePuy Synthes 2.4 mm Cannulated Screws, DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws, DePuy Synthes 4.5 mm Cannulated Screws, DePuy Synthes 6.5 mm Cannulated Screws, DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws, DePuy Synthes 1.5 mm Headless Compression Screws, DePuy Synthes 2.4 mm Headless Compression Screws, DePuy Synthes 3.0 mm Headless Compression Screws, DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screw - Zimmer, GmbH **K042695** Single/multiple component metallic bone fixation appliances and accessories, Smooth threaded metallic bone fixation fastener Zimmer, GmbH **K162124** Synthes 4.5mm VA-LCP Curved Condylar Plate System Line Extension, Variable Angle Positioning Pins - Depuy Synthes **K182718** - Mini and Micro Fragments Reconstruction System – GMReis - GM dos Reis Industria E Comercio Ltda

INDICATIONS FOR USE

The Versalock Periprosthetic Femur Plates System – GMReis is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the femur, including:

- Periprosthetic fractures
- Comminuted fractures

- Supracondylar fractures
- Trochanteric fractures
- Fractures in normal and osteopenic bone
- Non-unions and Malunions

DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for the Versalock Periprosthetic Femur Plates System which is composed of plates, screws and, a cerclage cable and related device.

The subject devices are designed for the treatment of femur fractures, particularly, periprosthetic femur fractures. The plates are available in the following design-types to be used according to the fracture location: Proximal and Distal Femur Periprosthetic Plates, Trochanteric Periprosthetic Plates and Condylar Femur Plates.

The plates are for use with the subject device screws to fix them to the bone. The following compatible screws are available for this purpose: Cortical Screws, Versalock Variable Angle Locking Screws, Versalock Variable Angle Screws, Versalock Variable Angle Cannulated Screws and Versalock Variable Angle Periprosthetic Screw. The Trochanteric Plate Fastening Screw is to connect one plate to another when a Trochanteric Periprosthetic Plates is used. The Versalock Spacer Screw is threaded into the plate hole prior to plate insertion to act as a spacer providing no contact between the plate and the bone surface.

The Gama Cable is a cerclage cable indicated to provide fixation and/or stabilization of the bone when it is not possible the usage of any screw. The Gama Cable related devices are the Gama Cable Lock and the Versalock Connector Screw. During the installation of the Cable, the Gama Cable Lock is crimped to lock the movement of the cable, maintaining the tensioning applied while the Versalock Connector Screw , which holds the cable to the plate and set the proper cable routing position. The Gama Cable and related devices are used in conjunction with the Proximal or Distal Femur Periprosthetic Plates, or Condylar Femur Plates

The subject devices are made of made of titanium alloy (ASTM F136) with exception of the Gama Cable Lock which it is made of commercially pure titanium (ASTM F67). All the subject devices are colored-anodized.

The devices must only be used by qualified surgeons mastering the surgical technique, having been trained and qualified in orthopedic surgeries.

EQUIVALENCE TO MARKETED DEVICE

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

K120772 - NCB Periprosthetic Trochanter Plates and Screws and NCB Cable Button for NCB Polyaxial Locking Plate - Zimmer, GmbH

The subject and predicate devices have equivalent intended use and equivalent technological characteristics. The subject and predicate devices are all manufactured from identical or equivalent materials and share equivalent design characteristics. The subject and predicate devices encompass equivalent physical dimensions and are to be sterilized by identical or equivalent method. Any difference in the technological characteristics do not raise new issues of safety or efficacy.

Biocompatibility was established through a risk assessment following ISO 10993-1.

The performance of the subject device plates was demonstrated through static and dynamic testing according to ASTM F382.

The performance of the subject screws was demonstrated through mechanical testing according to ASTM F543.

The performance of the cerclage cable was demonstrated through mechanical testing according to ASTM F2180 and system construct testing.

No clinical data were included in this submission.

The subject devices are provided non-sterile and have no expiration date defined.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate devices.