December 23, 2019

Gm Dos Reis Industria E Comerico Ltda.
% Paula Oliveira
Quality Manager
Passarini Regulatory Affairs of America, LLC
201 S. Biscayne Blvd. Suite 1200
Miami, Florida 33131

Re: K182718
Trade/Device Name: Mini and Micro Fragments Reconstruction 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, HWC
Dated: November 18, 2019
Received: November 21, 2019

Dear Paula Oliveira:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182718

Device Name

Mini and Micro Fragments Reconstruction System - GMReis

Indications for Use *(Describe)*

Mini and Micro Fragments Reconstruction System - GMReis is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand and wrist. The use of locking plate/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.

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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 130693-320 Telephone: +55 (19) 3765-9900
Contact Person	Paula Oliveira Quality Manager qualidade@gmreis.com.br Telephone: +55 (19) 3765-9900
Date Prepared	19/Dec/2019
Preparer / Alternate Contact	Janine Treter Regulatory Affairs Specialist Passarini Regulatory Affairs janine@rapassarini.com.br Telephone +55 (47) 3804 0075

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Mini and Micro Fragments Reconstruction System – GMReis
Common Names	Plate, Fixation, Bone
Classification Names	Single/multiple component metallic bone fixation appliances and accessories
Product Codes	HRS, HWC
Classification Regulations	21 CFR 888.3030, Class II
Review Panel	Orthopedic

PREDICATE DEVICE INFORMATION

Predicate Devices	K142419 - NEOORTHO Produtos Ortopédicos S/A - Neoortho Productos Orthopedicos S/A **(Primary Predicate)** K051567 – APTUS® Titanium Fixation System - Medartis, Inc. K100776 - Synthes 2.4mm12.7 mm Variable Angle LCP forefoot/. Midfoot system - Synthes (USA) LP K081546 - Small Bone Locking Plating System – DePuy Orthopaedics, Inc. K142906 - APTUS® Wrist 2.5 System – Medartis AG
Reference Device	K180626 – Pedimax II -Pedicular Screw Spinal System - GM dos Reis Indústria e Comércio Ltda

INDICATIONS FOR USE

Mini and Micro Fragments Reconstruction System - GMReis is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand and wrist. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone.

DEVICE DESCRIPTION

Mini and Micro Fragments Reconstruction System – GMReis is composed of plates and screws. The bone plates are made from commercially pure titanium and titanium alloy (Ti-4Al-6V) and the bone screws are manufactured from titanium alloy only. The plates range in thickness from 0.6 to 2.0 mm, and the screws range in diameter from 1.5 to 2.7 mm. They are available on different sizes and shapes, according the implantation site and the extension of the fracture.

Mini and Micro Fragments Reconstruction System – GMReis are for single use. The devices are provided non-sterile and must being properly cleaned and sterilized before use, according the recommendations provided in the Instructions for Use.

In order to promote a correct placement of the plates and screws, GMReis has also available a range of instruments (class I exempt) to serve the surgeon such as drills, drill guides, cutting pliers, reamers, screwdrivers, among others. GMReis recommends the use of these instruments in order to ensure the compatibility with the implants and promote the success of the procedure.

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

EQUIVALENCE TO MARKETED DEVICE

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

K142419 - NEOORTHO Produtos Ortopédicos S/A - Neoortho Productos Orthopedicos S/A
K051567 – APTUS® Titanium Fixation System - Medartis, Inc.
K100776 - Synthes 2.4mm12.7 mm Variable Angle LCP forefoot/.Midfoot system - Synthes (USA) LP
K081546 - Small Bone Locking Plating System – DePuy Orthopaedics, Inc.
K142906 - APTUS® Wrist 2.5 System – Medartis AG

The subject device and the predicate devices have the same intended use and have similar technological characteristics. The subject and predicate devices are all manufactured from the same or similar materials and share similar design characteristics, including plate screw holes to accommodate locking and non-locking screws. The subject and predicate devices encompass the same range of physical dimensions, are packaged using similar materials and are to be sterilized by the same methods. Any difference in the technological characteristics do not raise new issues of safety or efficacy.

Biocompatibility of the subject devices were supported by the tests required according to its contact profile as recommended by FDA guidance entitled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

The performance of the subject devices are demonstrated through mechanical testing of plates and screws according to ASTM F382 and ASTM F543, respectively.

The subject devices are provided non-sterile and have no expiration date defined. Steam sterilization validation was performed according to ISO 17665-1 and 17665-2.

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 device.