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.