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
Prepared by	Janine Treter and Graziela Brum Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: graziela@rapassarini.com.br Telephone +55 (16) 3421-8488
Submission date	29/Sep/2020

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	EXPERT – Joint Fixation System
Common Name	Washer, Bolt Nut
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Product Code	HTN
Classification Regulation	21 CFR 888.3030, Class II
Review Panel	Orthopedic

PREDICATE DEVICE INFORMATION

Predicate Devices	K090107 - Mini TightRope - Arthrex, Inc. K061925- Mini TightRopeTM Repair Kit - Arthrex, Inc. K043248 - Arthrex TightRope™ Syndesmosis Devices, Arthrex, Inc. K111032 - CMC Cable FIX - Instratek, Inc.
Reference Devices	K100006 – Polyester Non-absorbable Surgical Suture, Polyblend Non-absorbable Surgical Suture, Silk Non-absorbable Surgical Suture, Polypropylene Surgical Suture, Nylon Non-absorbable Surgical Suture, Riverpoint Medical K180626 - Pedimax II - Pedicular Screw Spinal System - GM dos Reis Industria E Comercio Ltda K182718 - Mini and Micro Fragments Reconstruction System – GMReis - GM dos Reis Industria E Comercio Ltda

INDICATIONS FOR USE

The EXPERT – Joint Fixation System is intended as an adjunct in fracture repair involving metaphyseal and periarticular bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and nails, with fracture braces and casting.

The Mini EXPERT, EXPERT Knotless and EXPERT Knotless Dual are intended to provide fixation during the healing process following:

Mini EXPERT
When used for fixation of bone-to-bone, the Mini EXPERT is intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon repair, such as:
- Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
- Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the reconstruction of the ligament at the base of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

EXPERT Knotless and EXPERT Knotless Dual
Syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

DEVICE DESCRIPTION

The EXPERT – Joint Fixation System is available in three models. Each model is composed of different medical devices (i.g. plates, surgical suture) assembled together for the purpose of use as a set. Each set is composed of plates from different sizes and shapes made of Titanium Alloy (ASTM F136) associated with non-absorbable surgical sutures and/or surgical meshes made of an Ultra-High Molecular Weight Polyethylene (UHMWPE).

The metallic components are manufactured by GM dos Reis Indústria e Comércio Ltda and the non-absorbable Surgical Sutures and Surgical Suture Meshes are purchased in bulk from River Point Medical (K100006).

Each EXPERT model comes with a transient use guidewire accessory in the same package. The guidewire is made of Stainless Steel (ASTM F138) to aid in the EXPERT – Joint Fixation System placement.

In order to promote a correct placement of EXPERT – Joint Fixation System, GMReis has also available a range of instruments (class I exempt) to serve the surgeon such as drill bits, drill guides, plier, among others. GMReis recommends the use of these instruments in order to ensure the compatibility with the subject devices 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 orthopedic surgeries.

EQUIVALENCE TO MARKETED DEVICE

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

K090107 - Mini TightRope - Arthrex, Inc.
K061925- Mini TightRope™ Repair Kit - Arthrex, Inc..
K043248 - Arthrex TightRope™ Syndesmosis Devices, Arthrex, Inc.
K111032 - CMC Cable FIX - Instratek, Inc.

The subject device and the 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 method. Any difference in the technological characteristics do not raise new issues of safety or efficacy.

Biocompatibility of the titanium alloy plates are supported by the reference devices K180626 and K182718. Biocompatibility of the UHMWPE surgical sutures are supported by the reference devices K100006. Biocompatibility of the stainless steel of the guide wire are supported for the following test reports: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity and Material-mediated Pyrogenicity Testing according the 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" dated June 16, 2016 according to the device categorization and contacting profile. Pyrogenicity monitoring according to AAMI/ANSI ST72 meeting pyrogen limit specifications.

The subject devices are provided sterile and have shelf life of 3 years. Ethylene oxide sterilization validation was performed according to ISO 11135.

The performance of the subject devices compared with the predicate devices are demonstrated through mechanical testing. No clinical data were included in this submission.

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.