October 29, 2020

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

Re: K200332
Trade/Device Name: EXPERT - Joint Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: September 29, 2020
Received: October 2, 2020

Dear Graziela Brum:

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,

Laura C. Rose, Ph.D.
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)*
K200332

Device Name
EXPERT – Joint Fixation System

Indications for Use *(Describe)*
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.

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 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:
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- 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.