August 2, 2023

Gm Dos Reis Industria E Comerico Ltda
% Homero Antunes
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Alem Saadi, 855/2402
Ribeirao Preto, Sao Paulo 14096570
Brazil

Re: K223114
Trade/Device Name: Suture Anchors - HTA Headless Titanium Anchor and Zip Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 7, 2023
Received: July 7, 2023

Dear Homero Antunes:

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,

Sara S. Thompson -S

For

Jesse Muir, 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)*
K223114

Device Name
Suture Anchors - HTA Headless Titanium Anchor and ZIP Anchors

Indications for Use *(Describe)*
The Suture Anchors - HTA Headless Titanium Anchor and ZIP Anchors are indicated to be used for suture or tissue fixation in the elbow, shoulder, hand, wrist, foot, ankle, knee, and hip. Specific indications are listed below:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hip: Capsular repair, acetabular labral repair.

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
Contact Person and Preparer	Homero Santiago Antunes Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: homero@passarini.com.br Telephone +55 (47) 3804 0075
Date Prepared	August, 1 2023

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Suture Anchors - HTA Headless Titanium Anchor and ZIP Anchors
Common Name	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Product Code	MBI
Classification Regulation	21 CFR 888.3040, Class II
Review Panel	Orthopedic

PREDICATE DEVICE INFORMATION

Predicate Devices	K180118 – Arthrex NanoSuture Anchor - Arthrex, Inc.
Reference Devices	K112237 – MicroSuture Anchors - Arthrex, Inc. K003816 - Titanium Fixation System - Arthrex, Inc. K061863 – Arthrex PushLock, Tak, and Corkscrew products - Arthrex, Inc. K110879 – JuggerKnotTM Mini Soft Anchors – Biomet Sports Medicine

K172612 – FiberTak DX - Arthrex, Inc.
K151230 – Arthrex FiberTak Anchors – Arthrex, Inc.
K181769 – Arthrex FiberTak Suture Anchor – Arthrex, Inc.
K200332 – Expert - Joint Fixation System – GM Dos Reis Industria E Comercio Ltda
K100006 – HS Fiber (Polyblend); RiverBond (Polyester); RiverSilk (silk); RiverPro (PP); RiverLon (Nylon) – Riverpoint Medical

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Hip: Capsular repair, acetabular labral repair.

DEVICE DESCRIPTION

The Suture Anchors, manufactured by GM dos Reis Indústria e Comércio Ltda, are anchor-type implants, and are composed of two groups of anchors, manufactured in Titanium Alloy (ASTM F136) and Ultra High Molecular Weight Polyethylene – UHMWPE (which are called ZIP Anchor), that is the same raw material of the suture. The anchors are made available preloaded in a disposable inserter device, composed of a metal rod and a polymeric cable. The implant and disposable inserter devices are unique products and cannot be sold separately.
Implants of the Suture Anchors - GM Reis are classified as surgically invasive, non-absorbable, and non-active implantable medical devices. In addition, the implants, as well as, the inserter device, are for single-use and sold in sterile form - supplied as a sterile kit for ethylene oxide (ETO) according to ISO 11135 - "Preview Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices".

The Suture Anchors - GM Reis is composed of two different groups of anchors:

- HTA – Headless Titanium Anchor.
    - Anchor Diameters: ø1,7 mm; ø2,2 mm; ø2,7 mm; ø3,5 mm and ø5,0 mm

- ZIP Anchor.
    - Ø0.9mm; Ø1.2mm; Ø1.5mm; Ø1.8mm; Ø1.9mm; Ø2.6mm.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The subject device is substantially equivalent in indications and design principles to the predicates identified before.
The subject and predicate devices have equivalent intended use and equivalent technological characteristics. The subject and predicate devices are all manufactured from identical materials and share equivalent design characteristics. The subject and predicate devices encompass equivalent physical dimensions. Any difference in the technological characteristics do not raise new issues of safety or efficacy. No clinical data were included in this submission.

NON-CLINICAL PERFORMANCE DATA:

The insertion torque and the pullout strength were selected for comparing the anchors performance. Statistical analysis was applied to demonstrate that the performance measured for the GM Reis anchors are equivalent to the predicate performance. The procedure for evaluating the compatibility with the magnetic resonance (MR) environment of the suture anchors were tested following current standards. To select the appropriate endpoints for biological evaluation, the chemical characteristics of the products, the nature, frequency, and duration of exposure to the body (i.e., intended use), were considered according to ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

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.