



November 4, 2025,

GM Dos Reis Industria e Comercio Ltda.
Guilherme Esteves Pontes
Senior Regulatory Affairs Analyst
Avenida Pierre Simon de Laplace, 600
Campinas, SP 13069320
Brazil

Re: K252664

Trade/Device Name: GMReis Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 18, 2025
Received: August 22, 2025

Dear Guilherme Esteves Pontes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252664

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Please provide the device trade name(s).

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GMReis Suture Anchors

Please provide your Indications for Use below.

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The GMReis Suture Anchors is intended to be used for soft tissue reattachment 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, 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, 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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Section 5 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter:

GM Dos Reis Industria e Comercio Ltda

Avenida Pierre Simon de La Place 600, Campinas, São Paulo, Brazil 13069-320

Guilherme Esteves Pontes, Senior Regulatory Affairs Analyst

Telephone: +55 (19) 3765-9900 / Email: qualidade4@gmreis.com.br

Date prepared: October 21, 2025

II. Device Name:

Trade Name: GMReis Suture Anchors

Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue

Regulation Description: Smooth or threaded metallic bone fixation fastener

Device Class: II

Product Codes: MBI

Regulation Number: 21 CFR 888.3040

III. Predicate Devices:

Legally marketed devices to which we are claiming "Substantial Equivalence" are the following:

Arthrex DX SwiveLock SL with Forket Eyelet 3.5 x 8.5mm, Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm (K150648) (Primary predicate device).

Arthrex PushLock Suture Anchors (K251145) (Additional predicate device).

Arthrex 2.5 mm Tenodesis Screw (K183395) (Additional predicate device).

SwiveLock Anchors (K101823) (Additional predicate device).

Arthrex Tenodesis Screw Family (K051726) (Additional predicate device).

EXPERT - Flexible Joint Fixation System - GMReis (K242311) (Reference device).

IV. Device Description:

The Suture Anchors, manufactured by GM dos Reis Industria e Comercio Ltda, are anchor-type implants, and are manufactured in PEEK (polyetheretherketone). The anchors are made available preloaded in a

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disposable inserter device, composed of a metal rod and a polymeric handle. The implant and disposable inserter devices are unique products and cannot be sold separately. Implants of the Suture Anchors 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 by Ethylene Oxide.

V. Statement of Indications for Use of the Device:

The GMReis Suture Anchors is intended to be used for soft tissue reattachment 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.

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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.

VI. Comparison of Technological Characteristics with The Predicate Device:

The subject and predicate devices have equivalent intended use and technological characteristics. Both are manufactured from identical materials and share equivalent design characteristics. All the devices encompass equivalent physical dimensions. Any difference in technological characteristics do not raise new issues of safety or efficacy. No clinical data were included in this submission.

VII. Performance Data:

The insertion test, pullout test and fatigue tests were conducted with the subject devices and compared with the predicate devices. Mechanical testing demonstrated that the strength of the proposed subject devices met the criteria established by literature and standards and its equivalent to the predicate devices.

VIII. Conclusions:

As was established in this submission, the subject GMReis Suture Anchors are substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics, intended use, indications for use, material composition, anatomical region, multiple sizes, and basic design features compared to its predicate devices. Any differences between the subject and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.