August 22, 2026

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

Re: K253910
Trade/Device Name: Stitch - Suture Wires and Tapes
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 16, 2026
Received: July 16, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.	K253910

Please provide the device trade name(s).

Stitch - Suture Wires and Tapes

Please provide your Indications for Use below.

Stitch - Suture Wires and Tapes are indicated for use in general soft tissue approximation and/or ligation.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary
(K253910)

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

I. Submitter:

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Email: qualidade4@gmreis.com.br
Date prepared: August 12, 2026

II. Device Name:

Trade Name:	Stitch - Suture Wires and Tapes
Common Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture
Device Class:	II
Product Codes:	GAT
Regulation Number:	21 CFR 878.5000

III. Predicate Devices:

Legally marketed devices to which we are claiming “Substantial Equivalence” is the following:
HS Fiber Sutures - Riverpoint Medical (K231163) (Primary)
Arthrex Suture - Arthrex Inc. (K122374) (Additional)
Stitch Cerclage - Suture Tapes - GMReis (K243905) (Reference Device)
EXPERT - Joint Fixation System - GMReis (K200332) (Reference Device)

IV. Device Description:

The purpose of this submission is to obtain marketing clearance for Stitch - Suture Wires and Tapes. Stitch - Suture Wires and Tapes are used in surgeries for approximations and for union of soft tissues until healing occurs. The surgical sutures and tapes are made of UHMWPE (ultra-high molecular weight polyethylene), and the needles are made in AISI300 steel series, according to the standard ASTM F899. They are found in a variety of diameters to meet the range of anatomies of the patients; it is provided in sterile condition sterilized by Ethylene Oxide. The sutures are classified as non-absorbable and meet the USP standards. This product is for single use only. This device comes in sizes USP 3-0, 2-0, 0, 1, 2 and 5 and suture tape sizes 1.3mm, 1.6mm and 2.0mm.

The color additives used are accepted by FDA, according to the guidance “Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices”; Color Additives Approved for Use in Medical Devices, as follows:

- Chromium-cobalt-aluminum oxide (CFR §73.1015) for the blue color in concentration lower than 2% by weight of the suture material.
- D&C Black (CFR §74.3054) for the black color in concentration lower than 1% by weight of the suture material.

V. Indications for Use of the Device:

Stitch - Suture Wires and Tapes are indicated for use in general soft tissue approximation and/or ligation.

VI. Comparison of Technological Characteristics with The Predicate Devices:

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

K231163 - HS Fiber Sutures - Riverpoint Medical

K122374 - Arthrex Suture - Arthrex Inc.

The subject and predicate devices have equivalent intended use and equivalent technological characteristics. They are all manufactured from identical materials and share equivalent design characteristics like physical dimensions. Any difference in the technological characteristics do not raise new issues of safety or efficacy. The performance of the subject device was compared with the specific FDA guidance and was demonstrated through mechanical testing according to USP standards and comparison side-by-side with the predicate. No clinical data were included in this submission. The subject device is provided sterile by Ethylene Oxide method. The sterilization process, parameters, validation and shelf life is the same as the reference device cleared under the 510(k) K243905 and K200332.

Specification	Subject Device GM Dos Reis Stitch - Suture Wires and Tapes	Primary Predicate Device Riverpoint (K231163) HS Fiber Sutures	Predicate Device Arthrex Inc. (K122374) Arthrex Suture	Reference Device GM Dos Reis (K243905) Stitch Cerclage - Suture Tapes	Reference Device GM Dos Reis (K200332) EXPERT - Joint Fixation System - GMReis
Indications for Use	Stitch - Suture Wires and Tapes are indicated for use in general soft tissue approximation and/or ligation.	HS Fiber sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues for orthopedic procedures.	The Arthrex Suture is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissue are used for repair.	Stitch Cerclage - Suture Tapes are indicated in orthopedic surgeries as bone fixation cerclage, specifically: • Sternotomy indications including the "rewiring" of osteomized sternums; • Repair of long bone fractures due to trauma or reconstruction.	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.
Materials	UHMWPE and Stainless Steel	UHMWPE and Stainless Steel	UHMWPE and Stainless Steel	UHMWPE and Stainless Steel	UHMWPE and Stainless Steel
Design	Braided Sutures	Braided Sutures	Braided Sutures	Braided Sutures	Braided Sutures
Performance Testing	USP Standards	USP Standards	USP Standards	USP Standards	USP Standards
Application Procedure	Soft tissue fixation	Soft tissue fixation	Soft tissue fixation	Soft tissue fixation	Soft tissue fixation
Presentation	Sterile	Sterile	Sterile	Sterile	Sterile
Regulation Name	Nonabsorbable poly(ethylene terephthalate) surgical suture	Nonabsorbable poly(ethylene terephthalate) surgical suture	Nonabsorbable poly(ethylene terephthalate) surgical suture	Bone Fixation Cerclage	Single/multiple component metallic bone fixation appliances and accessories.
Regulation Number	21 CFR 878.5000	21 CFR 878.5000	21 CFR 878.5000	21 CFR 888.3010	21 CFR 888.3030
Product Code	GAT	GAT	GAT	JDQ	HTN
Class	II	II	II	II	II
Sizes	Suture Wire: 3-0 / 2-0 / 0 / 1 / 2 and 5 Suture tape: 1.3 / 1.6 and 2.0mm	Suture Wire: 3-0 / 2-0 / 0 / 1 / 2 and 5 Suture tape: 1.3 / 1.6 and 2.0mm	Suture Wire: 3-0 / 2-0 / 0 / 1 / 2 and 5 Suture tape: 1.3 / 1.7 and 2.0mm	Suture tape: 2.5mm	Sutures from 2-0 to 5 Plates from Ø2.6 to Ø5.5

VII. Performance Data:

The non-clinical tests performed and the Recognized Consensus Standards to which the SStitch - Suture Wires and Tapes have been tested are specifically the following:

- Sutures - Diameter <861>
- Sutures - Needle Attachment <871>
- Tensile Strength <881>

Materials used were evaluated per ISO 10993-1:2018 – Biological Evaluation of Medical Devices. The subject device components are provided sterile. The sterilization method is ethylene oxide exposure. The EO sterilization has been validated to a sterility assurance level (SAL) of 10^{-6}, according to ISO 11135 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices. The shelf life is the same as the reference device cleared, and they share equivalent characteristics ensuring that no new worst-case scenario for shelf-life and sterilization is identified. The medical device in its final finished form is identical to Stitch Cerclage - Suture Tapes (K243905) (previously marketed device) in formulation, processing, design, sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, additives, additives, additives, cleaning agents, mold release agents).

VIII. Conclusions:

As was established in this submission, the subject Stitch - Suture Wires and Tapes 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.