February 19, 2026

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: K254188
Trade/Device Name: Meniscus Versaflex
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: December 22, 2025
Received: December 23, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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.	K254188

Please provide the device trade name(s).

Meniscus Versaflex

Please provide your Indications for Use below.

Meniscus Versaflex is indicated for repair of the meniscus.

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

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

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: December 22, 2025

II. Device Name:

Trade Name:	Meniscus Versaflex
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Regulation Description:	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” are the following:
Fast-fix Flex - Smith&Nephew (K203393) (Primary predicate device).
GMReis Suture Anchors - GMReis (K252664) (Reference device).

IV. Device Description:

Meniscus Versaflex - All Inside Meniscal Suture with Bendable Tip is an arthroscopy suture, non-absorbable, assembled in an insertion device. The inserter mechanism can be molded for better access to the posterior areas, medium region and anterior third of meniscus, with use of a bending tool and the options (models) of general use and reverse. Each device has two implants of non-absorbable polymer PEEK, previously connected with a UHMWPE suture and pre-assembled in an insertion system. The inserter is offered in a curved and reverse curved configuration. It is provided in sterile condition sterilized by Ethylene Oxide.

V. Statement of Indications for Use of the Device:

Meniscus Versaflex is indicated for repair of the meniscus.

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:

Mechanical tests were performed according to USP standards, compared to the predicate and procedures adopted in the technical-scientific literature, *"Biomechanical Testing of Meniscal Repairs Using the FiberStichTM, Smith & Nephew Fast-FixTM 360, and Zimmer Biomet JuggerStichTM Implants",* Arthrex Orthopedics Research and Developments, 2020. The procedure in this literature was used as a basis for the tests since no national standard was found from the ABNT – Associação Brasileira de Normas Técnicas committee, or international standards from the ISO – International Standardization Organization and ASTM – American Standardization for Testing and Materials committees, for testing the biomechanical performance of the product. No clinical or animal data were included in this submission. The tests performed were:

- Failure Load
- Displacement
- Suture Length
- Sutures Diameter
- Sutures Tensile Strength USP
- Suture Composition

The performance data demonstrates that Versaflex met performance specifications based on established acceptance criteria and in comparison to the predicate device. Therefore, the Versaflex is considered substantially equivalent to the currently marketed predicate.

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 Meniscus Versaflex 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, 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.