May 6, 2026

Ortobio S.A.
Tatiana Jabor Botura
Regulatory Affaris Specialist
PR Serviços Regulatórios Administrativos Ltda
Edifício Pórtico Sul - R. José Jaime Delibo, 160,
Nova Aliança
Ribeirão Preto, SP 14026-563
Brazil

Re: K253027
Trade/Device Name: Anchor with Fiber Wire and Disposable Inserter
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 07, 2026
Received: April 07, 2026

Dear Tatiana Jabor Botura:

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 Part 809; 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.	K253027

Please provide the device trade name(s).

Anchor with Fiber Wire and Disposable Inserter

Please provide your Indications for Use below.

The Ortobio Anchor with Fiber Wire and Disposable Inserter is intended to be used for suture or tissue fixation in the elbow, shoulder, hand, wrist, foot, ankle and knee. 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.

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)
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) ☐ Adults (22 years old and greater)

510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor/Manufacturer Name	Ortobio S.A. Av. Mauá, 1133 - Zona 03, Maringá - PR, 87050-020 Phone: +55 (44) 3269-5045
Consultants	Tatiana Jabor Botura and Letícia Teixeira Regulatory Affairs Specialists PR Serviços Regulatórios Administrativos Ltda Email: tatiana@passarini.com.br Telephone +55 (16) 988280027
Date Prepared	August 25, 2025

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Anchor with Fiber Wire and Disposable Inserter
Common Name	Bone Anchor
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Product Code	MBI
Classification Regulation	21 CFR 888.3040, Class II
Review Panel	Orthopedic

PREDICATE DEVICE INFORMATION

Predicate Devices	K223114 - Suture Anchors - HTA Headless Titanium Anchor and ZIP Anchors
Reference Device	K201083 - Parcus V-lox Titanium Suture Anchors, Parcus Miti Suture Anchors

Indications for use

The Ortobio Anchor with Fiber Wire and Disposable Inserter is intended to be used for suture or tissue fixation in the elbow, shoulder, hand, wrist, foot, ankle and knee. 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.

Subject Device Description

The Fiber Wire Anchor with Disposable Applicator is a sterile, single-use medical device composed of a titanium alloy anchor featuring an external threaded portion and a hexagonal head with a central hole designed for suture thread passage.

The product is packaged with one or two preloaded non-absorbable sutures and is preassembled into a disposable applicator. Optional configurations include disposable suture needles.

The applicator is comprised of a stainless-steel shaft (AISI 304), a polypropylene handle, and an O-ring located at the handle's distal end. The suture thread is made of ultra-high molecular weight polyethylene (UHMWPE), size 2 (0.5 mm). Disposable needles are made of stainless steel (ASTM F899).

The anchor is intended for the fixation of soft tissue to bone and is typically used in ligament and tendon repair procedures in the shoulder, foot, elbow, ankle, hand, and wrist. The anchor is manufactured from titanium alloy in accordance with ISO 5832-3:1997 – Implants for Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy.

Substantial Equivalence

A comparison between the subject device and predicates is presented in the table below:

Table 1. Substantial equivalence

	Subject Device	Predicate Device	Reference Predicate	
Trade Name information	Anchor with Fiber Wire and Disposable Inserter	Suture Anchors - HTA Headless Titanium Anchor and ZIP Anchors	Parcus V-lox Titanium Suture Anchors, Parcus Miti Suture Anchors	Equivalent Discussion
	Ortobio	GM dos Reis	Parcus Medical, LLC	-
K number	-	K223114	K201083	-
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	Equivalent
Product Code	MBI	MBI	MBI	Equivalent
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Equivalent
Class	II	II	II	Equivalent
Indications for Use	The Ortobio Anchor with Fiber Wire and Disposable Inserter is intended to be used for suture or tissue fixation in the elbow, shoulder, hand, wrist, foot, ankle and knee. 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	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	The Parcus Miti Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications: Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis,Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment. Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC. The Parcus V-loxTM Titanium Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended	Equivalent

	Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis	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.	for the following indications: Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis,Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment. Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC. Hip: Acetabular Labral Repair	
Anchor Diameter	ø1,7 mm; ø 1,9 mm, 2,0 mm; ø2,8 mm; ø4,0 mm; ø5,0 mm; ø5,5 mm	ø1,7 mm; ø2,2 mm; ø2,7 mm; ø3,5 mm and ø5,0 mm	Miti Suture Anchor: ø 2.0mm, ø 2.5mm and ø 3.5mm V-lox Titanium Suture Anchor: ø4.5mm, ø 5.0mm, ø 5.5mm and ø 6.5mm.	The specifications and dimensions of the device in question are within the range of the predicate and reference devices. Minor differences in dimensions do not raise any safety or efficacy concerns.
Suture (USP)	#2; #2-0	#1; #2; #0; #2-0; #3-0; #4-0	3-0 and #2	Equivalent
Anchor Material	Titanium (ASTM F136)	Titanium (ASTM F136)	Titanium (ASTM F136)	Equivalent
Suture Material	UHMWPE	UHMWPE	UHMWPE	Equivalent
Sterilization	Sterile	Sterile	Sterile	Equivalent
Use	Single use	Single use	Single use	Equivalent
Principle of operation	Fixation of soft tissue to the bone	Fixation of soft tissue to the bone	Fixation of soft tissue to the bone	Equivalent

Comparison of Technological Characteristics with the Predicate Device

The subject device, Ortobio Anchor with Fiber Wire and Disposable Inserter, is substantially equivalent in indications and design principles to the predicate and reference devices. The subject and predicate devices have equivalent intended use and share the same principle of operation for

soft tissue fixation to bone. They are all manufactured from titanium alloy (ASTM F136) and use UHMWPE sutures fixed by integrated eyelets, provided sterile and single use. The subject device dimensions and suture sizes are within the range of the predicate and reference devices. These differences do not raise new issues of safety or effectiveness. Any difference in technological characteristics do not raise new issues of safety or efficacy. No clinical data was included in this submission

Non-clinical performance data

This submission was prepared in accordance with the FDA Guidance "Bone Anchors - Premarket Notification (510(k)) Submissions" and the "Class II Special Controls Guidance Document: Surgical Sutures".

The Ortobio Anchor with Fiber Wire and Disposable Inserter was evaluated for use in the MR environment and determined to be MR Conditional, based on testing performed in accordance with the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" and applicable ASTM standards. Worst-case devices were tested for magnetically induced force, torque, RF heating, and image artifact, and the results established the MR system conditions suitable for safe use.

Performance testing endpoints included insertion torque, inclined insertion, quasi-static pullout, inclined pullout, and post-fatigue pullout, all performed in accordance with FDA guidance and ASTM standards. Statistical analysis using the TOST method and non-inferiority evaluation demonstrated that the performance of the Ortobio anchors is equivalent or not inferior to the predicate HTA Headless Titanium Anchor (K223114). The results consistently confirmed that no significant differences exist between the subject and predicate devices, supporting the conclusion of substantial equivalence in mechanical performance

Biological evaluation endpoints were selected in accordance with ISO 10993-1, considering the chemical characteristics of the device, as well as the nature, frequency, and duration of body contact associated with the intended use.

Sterilization was validated according to ISO 11135:2014 to achieve a SAL of 10^{-6}, with routine control and monitoring parameters established. Shelf life was supported by accelerated aging testing, demonstrating stability of the device for five years.

Conclusion

The documentation submitted in this premarket notification demonstrates that Anchor with Fiber Wire and Disposable Inserter has comparable features and performance and, therefore, is substantially equivalent to the predicate and reference device.