



February 24, 2026

OSSIO, Ltd.
% Dave McGurl
Vice President, Regulatory Affairs- Orthopedics
MCRA, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K254055

Trade/Device Name: OSSIOfiber® Suture Anchor

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: MAI

Dated: December 16, 2025

Received: December 17, 2025

Dear Dave McGurl:

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 Medical Device File (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,

Thomas Mcnamara -S

For: 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.

K254055

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Please provide the device trade name(s).

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OSSIOfiber® Suture Anchor

Please provide your Indications for Use below.

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The OSSIOfiber® Suture Anchors are indicated for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation, in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.
- Knee: Anterior Cruciate Ligament Repair (4.75-5.5 Anchors Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair and Meniscal Root Repair. Secondary or adjunct fixation of ACL/PCL reconstruction or repair (4.75 – 5.5 Anchors only).
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair (Tennis Elbow).

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](#))

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510(k) SUMMARY
OSSIOfiber® Suture Anchor

Submitter:

Ossio Ltd.

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Contact Person: Taly Lindner

Date Prepared: Dec 16, 2025

Regulatory Contact:

Dave McGurl

Vice President, Regulatory Affairs – Orthopedics

MCRA, LLC

803 7th St NW

Washington, DC 20001

Office: 202.552.5800

Name of Device: OSSIOfiber® Suture Anchor

Common or Usual Name: Fastener, Fixation, Biodegradable, Soft Tissue

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II, 21 C.F.R. § 888.3030

Product Code: MAI

Primary Predicate: OSSIOfiber® Suture Anchor (K251309)

Reference Devices: OSSIOfiber® Pin Product Family, OSSIOfiber® Compression Screw, OSSIOfiber® Trimmable Fixation Nail (K231272)
OSSIOfiber® Suture Anchor 2.5-3.5 mm (K243760)
OSSIOfiber® Interference Screw (K252022)

Purpose of Submission

This traditional 510(k) premarket notification is being submitted to add the pediatric patient sub population, children (2-12 years) and adolescents (12-21 years), to the indications for use statement of the OSSIOfiber® Suture Anchors previously cleared under K251309.

Device Description

The OSSIOfiber® Suture Anchor consists of an eyelet and anchor body preloaded on an inserter. The anchor body and eyelet are made from poly (L-lactide-co-D,L-lactide) (PLDLA) reinforced with continuous mineral fibers. OSSIOfiber® implants have been shown to be biocompatible. The polymer content degrades by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The fibers are made from minerals that are found in natural bone. As the OSSIOfiber® implants degrade, the load transfers to the surrounding anatomy throughout the healing period of the bone. Substantial degradation takes place within approximately 18 months as shown in pre-clinical

studies, thus eliminating the requirement for future hardware removal surgery. Sutures, needles and suture snare may also be provided with the device depending on configuration.

The OSSIOfiber® Suture Anchors are sterile, single-use, and non-pyrogenic.

Indications For Use

The OSSIOfiber® Suture Anchors are indicated for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation, in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.
- Knee: Anterior Cruciate Ligament Repair (4.75-5.5 Anchors Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair and Meniscal Root Repair. Secondary or adjunct fixation of ACL/PCL reconstruction or repair (4.75 – 5.5 Anchors only).
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair (Tennis Elbow).

Summary of Technological Characteristics

The OSSIOfiber® Suture Anchors have identical intended use, material composition, design characteristics, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use as their predicate device (K251309). The OSSIOfiber® subject device include indications for use in pediatric patients, which are not present in the predicate device (K251309). The devices are available in sizes appropriate for the children and adolescents patient population. The difference in the identified patient population does not alter the intended use, as the design, materials, and performance characteristics are appropriate for both adult and pediatric applications. Thus, any differences between the subject devices and their predicates do not raise different questions of safety and effectiveness.

Non-Clinical Data

Biocompatibility for the subject device was established within the predicate clearance (K251309). Biocompatibility for the additional children and adolescents patient population was established primarily based on the referenced ISO 10993 data from the previously cleared reference devices (K231272, K243760, K252022) as well as a rationale. Additional mechanical performance testing

was not performed as the indications for use of the subject device do not present a new worst case compared to the cleared OSSIOfiber® predicate.

Conclusions

The OSSIOfiber® Suture Anchor has identical intended use, material composition, design characteristics, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use as its predicate device (K251309). The addition of children and adolescents patients to the indications for use raises no new issues of safety or effectiveness. The subject devices are available in sizes appropriate for the children and adolescents patient population. The subject devices have identical intended use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use including the children and adolescents patient population, as their reference devices (K243760, K252022). The addition of children and adolescents patients to the indications for use does not affect safety and effectiveness when used as labeled. Thus, OSSIOfiber® Suture Anchor is substantially equivalent to its predicate devices.