May 27, 2025

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

Re: K251309
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: April 21, 2025
Received: April 28, 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 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.	K251309

Please provide the device trade name(s).

OSSIOfiber® Suture Anchor

Please provide your Indications for Use below.

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

510(k) SUMMARY

OSSIO*fiber*® Suture Anchor

Submitter

Ossio Ltd.

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Contact Person: Taly Lindner

Date Prepared: Apr. 21, 2025

Name of Device: OSSIO*fiber*® 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

Predicate Devices

OSSIO*fiber*® Suture Anchor (K213415)- **Primary Predicate**
Arthrex SwiveLock Anchors (K192441)- Additional Predicate

Purpose of the Submission

This Special 510(k) premarket notification is submitted to expand the indications for use of the OSSIO*fiber*® Suture Anchor cleared under K213415 to include Meniscal Root Repair.

Device Description

The OSSIO*fiber*® 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. OSSIO*fiber*® 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 OSSIO*fiber*® 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 OSSIO*fiber*® Suture Anchors are sterile, single-use, and non-pyrogenic.

Indications for Use

The OSSIO*fiber*® Suture Anchors are indicated for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, 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 OSSIO*fiber*® Suture Anchors, have identical intended use, material composition, design characteristic, principles of operation, manufacturing and sterilization methods (sterilized by EtO) as the primary predicate device (K213415). The subject device and primary predicate device have identical indications for use except for the additional Meniscal Root Repair indication. The OSSIO*fiber*® Suture Anchor has the same intended use, principles of operation, and similar material composition and design characteristics as the additional predicate device Arthrex SwiveLock Anchor (K192441). The subject device has similar indications for use as the additional predicate device Arthrex SwiveLock Anchor (K192441), which includes the Meniscal Root Repair indication. Both the device and the additional predicate are supplied sterile, both sterilized by EtO. Although there are slight design and material composition differences between the subject device and the additional predicate, previously provided non-clinical performance testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIO*fiber*® Suture Anchor and its predicate devices do not raise different questions of safety and effectiveness.

Non-Clinical Data

A rationale was provided to support the addition of the Meniscal Root Repair indication, which was based on the comparative static pull-out and cyclic pull-out testing included within K213415. No additional non-clinical data is being provided within this submission.

Biocompatibility and magnetic resonance (MR) safety compatibility was established within the primary predicate submission (K213415).

Conclusions

The OSSIO*fiber*® Suture Anchors, have identical intended use, material composition, design characteristics, principles of operation, manufacturing and sterilization methods as the primary predicate device. The subject device and primary predicate device have identical indications for use except for the additional Meniscal Root Repair indication. The subject device has the same intended use, principles of operation and similar material composition, sterilization methods, design characteristics and indications for use (including the Meniscal Root Repair) as the additional predicate device. The addition of the Meniscal Root Repair indication was supported by a rationale based on previously provided non- clinical data. Any differences between the subject device and its predicate devices do not raise different questions of safety and effectiveness. Thus, the OSSIO*fiber*® Suture Anchor is substantially equivalent to its predicate devices.