August 19, 2025

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

Re: K252022
Trade/Device Name: OSSIOfiber® Interference Screw
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: June 30, 2025
Received: June 30, 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, 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.	K252022

Please provide the device trade name(s).

OSSIOfiber® Interference Screw

Please provide your Indications for Use below.

The OSSIOfiber® Interference Screws, are indicated for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone 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. Interference fixation is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate; Specifically:

• Shoulder: Rotator Cuff Repairs, 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, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

• Knee: Repair/Reconstruction of the Anterior Cruciate Ligament, Posterior Cruciate Ligament, Medial Collateral Ligament, Lateral Collateral Ligament, Patellar Tendon, Posterior Oblique Ligament, Iliotibial Band Tenodesis, MPFL

• Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

• Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist

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
OSSIOfiber® Interference Screw

Submitter:

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Contact Person: Taly Lindner
Date Prepared: August 19, 2025

Regulatory Contact:

Dave McGurl
Vice President, Regulatory Affairs – Orthopedics
MCRA, LLC
803 7th St NW, Floor 3
Washington, DC 20001
Office: 202.552.5800

Name of Device: OSSIOfiber® Interference Screw

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:	Arthrex FastThread Interference Screw (K202535)
Additional Predicate:	MILAGRO BR Interference Screws (5x23mm, 5x30mm, 6x23mm, 6x30mm) (K240441)
Reference Devices:	OSSIOfiber® Pin Product Family, OSSIOfiber® Compression Screw, OSSIOfiber® Trimmable Fixation Nail (K231272) OSSIOfiber® Small Suture Anchor 2.5-3.5 mm (K243760) OSSIOfiber® Suture Anchor (K251309)

Purpose of Submission

This traditional 510(k) premarket notification is being submitted to obtain clearance for the OSSIOfiber® Interference Screw.

Device Description

The OSSIOfiber® Interference Screw is an orthopedic implant made of poly (L-lactide-co-D,L-lactide) (PLDLA) reinforced with continuous mineral fibers. The OSSIOfiber® Interference Screws are cannulated and fully threaded, available in diameters ranging from 6 to 12 mm and lengths from 23 to 28 mm. 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 implantation site. Substantial degradation takes place within approximately 18 months as shown in pre-clinical studies, thus eliminating the requirement for future hardware removal surgery.

The OSSIOfiber® Interference Screw is supplied sterile, for single patient use only.

The OSSIOfiber® Interference Screw is designed to be used with commonly available orthopedic surgical tools such as ISO 9714 compatible instrumentation such as ISO 9714 compatible instrumentations.

Indications For Use

The OSSIOfiber® Interference Screws, are indicated for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone 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. Interference fixation is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate; Specifically:

- Shoulder: Rotator Cuff Repairs, 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, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle
- Knee: Repair/Reconstruction of the Anterior Cruciate Ligament, Posterior Cruciate Ligament, Medial Collateral Ligament, Lateral Collateral Ligament, Patellar Tendon, Posterior Oblique Ligament, Iliotibial Band Tenodesis, MPFL
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist

Summary of Technological Characteristics

The OSSIOfiber® Interference Screws have the same intended use, and principles of operation, and similar indications for use, material composition and design characteristics as the predicate devices (K202535, K240441). The indications of the subject device are identical to the primary predicate (K202535), except slightly different wording relating to the repair/reconstruction of the knee, which is similar to the wording of the additional predicate (K240441). The OSSIOfiber® Interference Screws include indications for use in pediatric patients, which are not present in the predicate device (K202535, K240441). 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. The OSSIOfiber® Interference Screws have identical intended use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use as their reference devices (K251309, K243760). The material, manufacturing and sterilization methods of the subject device are also the same as that of the cleared K231272 reference device. The OSSIOfiber® subject devices are available in sizes appropriate for the children and adolescents patient population. Although there are slight design and material differences compared to the primary predicate, mechanical testing demonstrated at least equivalent performance both initially and after in-vitro degradation. Thus, any differences between the subject devices and their predicates do not raise different questions of safety and effectiveness.

Non-Clinical Data

Pull-out testing was performed to verify the strength and fixation properties of the OSSIOfiber® Interference Screws, and to compare them to those of the primary predicate device (K202535). Testing was done initially

and following in-vitro degradation. The in-vitro degradation profile was characterized. Torsional strength and driving torque testing at time zero were also conducted for the OSSIOfiber® Interference Screws.

Biocompatibility for the subject device was established primarily based on the referenced ISO 10993 data from the previously cleared reference devices (K231272, K251309, K243760) and a rationale.

Conclusions

The OSSIOfiber® Interference Screw is as safe and effective as its primary predicate device, Arthrex FastThread Interference Screw (K202535). The OSSIOfiber® Interference Screw have the same intended use, and principles of operation, and similar indications for use, material composition and design characteristics as the predicate devices. The OSSIOfiber® Interference Screw have identical intended use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO), and similar indications for use as their reference devices (K251309, K243760). Any minor differences do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. Non-clinical testing data demonstrate that the OSSIOfiber® Interference Screw is at least as safe and effective as the primary predicate device. Thus, the OSSIOfiber® Interference Screw is substantially equivalent to its predicate devices.