May 1, 2026

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

Re: K254077
Trade/Device Name: OSSIOfiber® Threaded Trimmable Fixation Nail
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 27, 2026
Received: March 27, 2026

Dear Mr. 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 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 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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. | K254077 |

Please provide the device trade name(s).

OSSIOfiber® Threaded Trimmable Fixation Nail

Please provide your Indications for Use below.

OSSIOfiber® Threaded Trimmable Fixation Nails are indicated for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis, and bone grafts, of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization 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.

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

## OSSIO*fiber*® Threaded Trimmable Fixation Nail

**Submitter:**

**Ossio Ltd.**
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Contact Person: Taly Lindner
Date Prepared: Mar 23, 2026

**Regulatory Contact:**

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

**Name of Device:** OSSIO*fiber*® Threaded Trimmable Fixation Nail

**Common or Usual Name:** Screw, Fixation, Bone

**Classification Name:** Smooth or threaded metallic bone fixation fastener

**Regulatory Class:** Class II, 21 C.F.R. § 888.3040

**Product Code:** HWC

### Predicate Device

OSSIO*fiber*® Threaded Trimmable Fixation Nail (K241277) - Primary Predicate

OSSIO*fiber*® Compression Screw (K231272)- Additional Predicate

### Purpose of the Submission

This traditional 510(k) premarket notification is submitted to obtain clearance for a line extension having the same design characteristics, made of the same material, but of larger sizes outside the previously cleared range of the OSSIO*fiber*® Threaded Trimmable Fixation Nail family (K241277).

### Device Description

The OSSIO*fiber*® Threaded Trimmable Fixation Nails are threaded cannulated bone fixation implants made of degradable poly (L-lactide-co-D, L-lactide) (PLDLA) reinforced with continuous mineral fibers. The polymer content degrades by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The fibers are made of 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 osteotomy, fusion, or fracture. Substantial degradation takes place within approximately 18 months as shown in pre-clinical studies, thus eliminating the requirement for future hardware removal surgery.

The OSSIO*fiber*® Threaded Trimmable Fixation Nails are supplied sterile, for single patient use only. The implants are available in several sizes and designs. The implants are fully or partially threaded and have a beveled, headed or headless design. The additional devices included in this submission are: 70-100 mm long, and 7.0 mm in diameter.

The OSSIO*fiber*® Threaded Trimmable Fixation Nails are designed to be used with commonly available orthopedic surgical tools such as ISO 9714 compatible instruments.

**Indications for Use**

OSSIO*fiber*® Threaded Trimmable Fixation Nails are indicated for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis, and bone grafts, of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization 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.

**Summary of Technological Characteristics**

The OSSIO*fiber*® Threaded Trimmable Fixation Nails have identical intended use, indications for use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO) and design characteristics as the primary predicate device (K241277) but are larger and longer devices. The subject devices have identical intended use, indications for use, material composition, principles of operation, manufacturing and sterilization methods, and similar design characteristics as the additional predicate device OSSIO*fiber*® Compression Screw (K231272). The subject devices include larger sizes outside the previously cleared range. These additional sizes are similar to those of the additional predicate, the OSSIO*fiber*® Compression Screw. Thus, any differences between the OSSIO*fiber*® Threaded Trimmable Fixation Nails and its predicate devices do not raise different questions of safety and effectiveness.

**Non-Clinical Data**

The additional sizes in scope of the current submission do not introduce a new performance worst-case relative to the cleared primary predicate (K241277). The in-vitro degradation profile (i.e., change in material properties), pull-out and flexural bending properties referenced within K241277, remain applicable to the subject device. Confirmatory torsional strength and driving torque testing at time zero for the subject device were provided. Axial pull-out strength was also evaluated using an engineering analysis confirming that the subject device is substantially equivalent to the additional predicate, the OSSIOfiber® Compression Screw (K231272).

Biocompatibility for the implants was established primarily based on the referenced ISO 10993 data from the previously cleared predicates as well as a rationale. Magnetic resonance (MR) safety compatibility was established within the primary predicate submission (K241277).

**Conclusions**

The OSSIO*fiber*® Threaded Trimmable Fixation Nails are as safe and effective as their primary predicate device. The subject devices have identical intended use, indications for use, material composition, principles of operation, manufacturing and sterilization methods (sterilized by EtO) and design characteristics as the primary predicate device (K241277) but are larger and longer devices. The subject devices have identical intended use, indications for use, material composition, principles of operation, manufacturing and sterilization methods, and similar design characteristics as the additional predicate device OSSIO*fiber*® Compression Screw (K231272). The additional sizes, outside the previously cleared range, are similar to those of the additional predicate. The devices in scope of the submission do not introduce a new performance worst-case relative to the cleared primary predicate. Torsional strength and driving torque testing as well as an engineering analysis for axial pull-out strength demonstrate that the OSSIO*fiber*® Threaded Trimmable Fixation Nails are substantially equivalent to their predicates (K231272, K241277). The additional sizes in scope of this submission do not alter the intended surgical use of the device and do not affect their safety and effectiveness when used as labeled. Thus, the OSSIO*fiber*® Threaded Trimmable Fixation Nail is substantially equivalent to its predicate devices.