July 3, 2024

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

Re: K241277
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: May 6, 2024
Received: May 6, 2024

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 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241277

Device Name

OSSIOfiber® Threaded Trimmable Fixation Nail

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

OSSIO*fiber*® Threaded Trimmable Fixation Nail

Submitter

Ossio Ltd.

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Contact Person: Taly Lindner

Date Prepared: June 27, 2024

Regulatory Contact

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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 Devices

OSSIOfiber® Threaded Trimmable Fixation Nail (K233198) - Primary Predicate

OSSIO*fiber*® Cannulated Trimmable Fixation Nail (K203465, K231272) - Additional Predicate

Purpose of the Submission

This traditional 510(k) premarket notification is being submitted to allow for additional compatible instrumentation for the OSSIOfiber® Threaded Trimmable Fixation Nails cleared in K233198.

Device Description

The OSSIOfiber® 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 OSSIOfiber® 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 OSSIOfiber® Threaded Trimmable Fixation Nails are supplied sterile, for single patient use only. The implants are available in several sizes and designs.

The OSSIOfiber® 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, design characteristic, principles of operation, manufacturing and sterilization methods (sterilized by EtO) as the primary predicate device (K233198). The subject device has identical intended use, material composition, principles of operation, manufacturing and sterilization methods, and similar indications for use and design characteristic as the additional predicate device (K203465, K231272). Although there are differences between the subject device and the additional predicate device in regards to design, mechanical pull-out testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIO*fiber*® Threaded Trimmable Fixation Nail and its predicate devices do not raise different questions of safety and effectiveness.

Non-Clinical Data

Mechanical pull-out testing was performed to verify the fixation and strength properties of the OSSIO*fiber*® Threaded Trimmable Fixation Nail, and to compare them to those of the additional predicate device (K203465, K231272). Testing was done initially and following in-vitro degradation.

Biocompatibility and magnetic resonance (MR) safety compatibility was established within the primary predicate submission (K233198).

Conclusions

The OSSIO*fiber*® Threaded Trimmable Fixation Nails are as safe and effective as their predicate devices. The OSSIOfiber® Threaded Trimmable Fixation Nails, have identical intended use, indications for use, material composition, design characteristic, principles of operation, manufacturing and sterilization methods (sterilized by EtO) as the primary predicate device (K233198). The subject device has identical intended use, material composition, principles of operation, manufacturing and sterilization methods, and similar indications for use and design characteristic as the additional predicate device (K203465, K231272). Any minor design differences relative to the additional predicate 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 OSSIO*fiber*® Threaded Trimmable Fixation Nails are at least as safe and effective as their predicate devices (K233198, K203465, K231272). Thus, the OSSIO*fiber*® Threaded Trimmable Fixation Nails are substantially equivalent to it's predicate devices.