August 28, 2024

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

Re: K241932
Trade/Device Name: OSSIOfiber® Compression Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MNU
Dated: July 1, 2024
Received: July 1, 2024

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.

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*

K241932

Device Name

OSSIOfiber® Compression Staple

Indications for Use *(Describe)*

The OSSIOfiber® Compression Staple is indicated for fixation of arthrodesis, osteotomies and fractures in hand or foot surgery 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. The number and size of the OSSIOfiber® Compression Staples must be adapted to the indication.

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
OSSIOfiber® Compression Staple

Submitter:

Ossio Ltd.
8 HaTochen Street, Caesarea, Israel, 3079861
Phone: +972-4-9986600
Facsimile: +972-4-9986601
Contact Person: Taly Lindner
Date Prepared: July 1, 2024

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® Compression Staple

Common or Usual Name: Staple, Absorbable

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

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

Product Code: MNU

Primary Predicate:	OSSIOfiber® Compression Staple (K233302)
Additional Predicates:	OSSIOfiber® Compression Staple (K212594) EasyClip® and EasyClip® Xpress (K210582)
Reference Devices:	OSSIOfiber® Pin Product Family, OSSIOfiber® Compression Screw, OSSIOfiber® Trimmable Fixation Nail (K231272)

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 of OSSIOfiber® Compression Staples previously cleared under K212594, K233302.

Device Description

The OSSIOfiber® Compression Staple is a fixation implant 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 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 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® Compression Staples are supplied sterile, for single patient use only. They are available in several sizes: 9-25 mm bridge lengths, and 10-22 mm leg lengths.

The OSSIOfiber® Compression Staples are designed to be used with commonly available orthopedic surgical tools such as ISO 9714 compatible instrumentations.

Indications For Use

The OSSIOfiber® Compression Staple is indicated for fixation of arthrodesis, osteotomies and fractures in hand or foot surgery 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. The number and size of the OSSIOfiber® Compression Staples must be adapted to the indication.

Summary of Technological Characteristics

The OSSIOfiber® Compression Staples 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 devices (K212594, K233302). All devices are available in sizes appropriate for the children and adolescents patient population. The OSSIOfiber® subject devices have similar indications for use including the children and adolescents patient population, and similar design characteristics as the additional predicate device (K210582). 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 implants was established within the predicate clearances K212594, K233302. 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) 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® predicates.

Conclusions

The OSSIOfiber® Compression Staples 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 devices (K212594, K233302). The addition of children and adolescents patients to the indications for use raises no new issues of safety or effectiveness. All devices are available in sizes appropriate for the children and adolescents patient population. The OSSIOfiber® Compression Staples have similar indications for use including the children and adolescents patient population, and similar design characteristics as the additional predicate device (K210582). The addition of children and adolescents patients to the indications for use does not affect safety and effectiveness when used as labeled. Thus, the OSSIOfiber® Compression Staples are substantially equivalent to their predicate devices.