November 16, 2023

Ossio Ltd.
% David Mcgurl
Vice President, Regulatory Affairs - Orthopedics
Mcra, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K233302
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: September 29, 2023
Received: September 29, 2023

Dear David 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K233302

Device Name

OSSIOfiber® Compression Staple

Indications for Use *(Describe)*

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.

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.

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Contact Person: Taly Lindner
Date Prepared: September 29, 2023

Name of Device: OSSIO*fiber*® 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

Predicate Devices

OS2®-VP Varisation Staple (K153770) - Primary Predicate

OSSIOfiber® Compression Staple (K212594)

Reference Device

OSSIOfiber® Cannulated Trimmable Fixation Nail (K203465)

OSSIO*fiber*® Compression Screw (K193660, K213596, K221193)

Purpose of Submission

This traditional 510(k) premarket notification is being submitted to obtain clearance for an additional smaller Compression Staple design, made from the same material as the OSSIOfiber® Compression Staple family (named OSSIOfiber® Compression Staple, 9 x 10mm and 11 x 10mm).

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. OSSIOfiber® 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 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® Compression Staples are supplied sterile, for single patient use only, and non-pyrogenic. The additional devices included in this submission are: 9 x 10mm, and 11 x 10 mm.

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

Indications for Use

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.

The number and size of the OSSIOfiber® Compression Staples must be adapted to the indication.

Summary of Technological Characteristics

The OSSIOfiber® Compression Staples have the same intended use, and similar indications for use, principles of operation and design characteristics as the primary predicate device the OS2®-VP Varisation Staple (K153770). The OSSIOfiber® Compression Staples have the same intended use, indications for use, material composition, manufacturing and sterilization methods, principles of operation, and similar design characteristics as the predicate device (K212594). Both subject device and the primary predicate device are supplied sterile. The OSSIOfiber® Staple is sterilized by EtO whereas the primary predicate is sterilized by Gamma. Although there are differences with regards to polymeric material, shape and size compared to the primary predicate, mechanical testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIOfiber® Staple and its predicate devices do not raise different questions of safety and effectiveness.

The OSSIOfiber® Compression Staples' material as well as the manufacturing and sterilization methods are the same as that of the predicate (K212594) and the cleared reference devices (K203465 and K193660 K213596, K221193). Subject, predicate and reference devices are supplied sterile, sterilized by EtO .

Non-Clinical Data

Static bending, bending fatigue and pull-out testing were performed to verify the strength and fixation properties of the OSSIOfiber® Compression Staple, and to compare them to those of the primary predicate device, the OS2®-VP Varisation Staple (K153770). Testing on the subject device were done initially and following in-vitro degradation. The in-vitro degradation profile was characterized.

Biocompatibility for the implants was established primarily based on the referenced ISO 10993 data from the previously cleared predicate and reference devices (K212594, K203465) as well as a rationale. A rationale was provided to support the MR safe labeling of the implant.

Conclusions

The OSSIOfiber® Compression Staple is as safe and effective as its predicate devices (K212594, K153770). The subject device has the same intended use, and similar indications for use, principles of operation and design characteristics as the primary predicate device the OS2®-VP Varisation Staple (K153770). The subject device has the same intended use, indications for use, material composition, manufacturing and sterilization methods, principles of operation, and similar design characteristics as the predicate device (K212594). The minor design differences and additional sizes do not alter the intended surgical use of the implant and do not affect its safety and effectiveness when used as labeled. Non-clinical testing data demonstrate that the OSSIOfiber® Compression Staple is at least as safe and effective as the primary predicate device. Thus, the OSSIOfiber® Compression Staple is substantially equivalent.