January 21, 2022

OSSIO Ltd.
% David McGurl
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K212594
Trade/Device Name: OSSIOfiber® 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: January 10, 2022
Received: January 10, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
Acting 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)*
K212594

Device Name
OSSIOfiber® Staple

Indications for Use *(Describe)*
The OSSIOfiber® 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® 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.

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510(k) SUMMARY

OSSIO*fiber*® Staple

Submitter

Ossio Ltd.

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Contact Person: Taly Lindner
Date Prepared: Jan 16, 2022

Name of Device: OSSIO*fiber*® 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®-C Compression Staple (K153395) – **Primary Predicate**

Reference Devices

OSSIO® Pin Product Family (K181180)
OSSIO*fiber*® Hammertoe Fixation System (K190652, K201803)
OSSIO*fiber*® Compression Screw (K193660)

Device Description

The OSSIO*fiber*® Staple is a fixation implant made of degradable poly (L-lactide-co-D,L-lactide) (PLDLA) reinforced with continuous mineral fibers. OSSIO*fiber*® 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 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*® Staples are supplied sterile, for single patient use only, and non-pyrogenic. They are available in several sizes: 11-25 mm bridge lengths, and 15-22 mm leg lengths.

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

Indications for Use

The OSSIO*fiber*® 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 OSSIO*fiber*® Staples must be adapted to the indication.

Summary of Technological Characteristics

The OSSIO*fiber*® Staples have the same intended use, and similar indications for use, principles of operation and design characteristics as the primary predicate device the OS2®-C Compression Staple (K153395).

The OSSIO*fiber*® Staples' material composition as well as the manufacturing and sterilization methods are the same as that of the cleared reference devices the OSSIO® Pin Product Family (K181180), OSSIO*fiber*® Hammertoe Fixation System (K190652, K201803) and OSSIO*fiber*® Compression Screw (K193660). Both subject device and the primary predicate device are supplied sterile. The OSSIO*fiber*® Staple is sterilized by EtO whereas the primary predicate is sterilized by Gamma. The subject device is made of OSSIO*fiber*® material while the primary predicate is made of PEEK. The OSSIO*fiber*® Staple has slightly longer leg and bridge lengths compared to the primary predicate. Although there are differences with regards to 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 OSSIO*fiber*® Staple and its primary predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Data

Static bending, bending fatigue and pull-out testing were performed as per ASTM F564-17 to verify the bending strength and stiffness, bending fatigue strength, and pull-out fixation properties of the OSSIO*fiber*® Staple. Static bending and bending fatigue were compared to those of the primary predicate device (K153395). Pull-out testing was compared to those of the K181180 reference device. All testing 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 reference devices (K181180, K190652, K193660, K201803) as well as a rationale. A rationale was provided to support the MR safe labeling of the implant.

Conclusions

The OSSIO*fiber*® Staple is as safe and effective as its primary predicate device, the OS2®-C Compression Staple (K153395). The OSSIO*fiber*® Staples have the same intended use, and similar indications for use, principles of operation, and design characteristics as the primary predicate device the OS2®-C Compression Staple (K153395). Material composition is the same as the reference devices (K181180, K193660, K190652, K201803). The minor differences 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 OSSIO*fiber*® Staple is at least as safe and effective as the primary predicate device. Thus, the OSSIO*fiber*® Staple is substantially equivalent.