



December 21, 2021

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

Re: K213596

Trade/Device Name: OSSIO*fiber*® Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 12, 2021
Received: November 12, 2021

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,

Shumaya Ali, MPH
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: 06/30/23
See *PRA Statement below*.

510(k) Number (if known)

K213596

Device Name

OSSIOfiber® Compression Screw

Indications for Use (Describe)

OSSIOfiber® Compression Screws 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.

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**OSSIOfiber® Compression Screw, 3.5mm****Submitter****Ossio Ltd.**

8 HaTochen Street, Caesarea, Israel, 3079861

Phone: +972-4-9986600

Facsimile: +972-4-9986601

Contact Person: Taly Lindner

Date Prepared: November 12, 2021

Name of Device: OSSIOfiber® Compression Screw, 3.5mm

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® Compression Screw (K193660) - **Primary Predicate**

Tyber Medical Compression Screw (K133842)

Reference Devices

OSSIOfiber® Cannulated Trimmable Fixation Nail (K203465)

Purpose of Submission

This traditional 510(k) premarket notification is submitted to obtain clearance for an additional screw design made of the same material including lengths outside the previously cleared range of the OSSIOfiber® Compression Screw family (named OSSIOfiber® Compression Screw, 3.5mm).

Device Description

The OSSIOfiber® Compression Screws are cannulated bone screws 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® Compression Screws are supplied sterile, for single patient use only. The screws are partially threaded and have a cannulated design. The additional devices included in this submission are: 14- 50 mm long, and 3.5 mm diameter.

The OSSIOfiber® Compression Screws are designed to be used with commonly available orthopedic surgical tools such as ISO 5835/ISO 9714 compatible instrumentations.

Indications for Use

OSSIOfiber® Compression Screws 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.

Summary of Technological Characteristics

The OSSIOfiber® Compression Screws, 3.5mm have the same intended use, indications for use, material composition, manufacturing and sterilization methods and principles of operation as the primary predicate device (K193660). Although there are differences with regards to shape and length as compared to the predicate devices, mechanical pull-out testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIOfiber® Compression Screws, 3.5mm and its predicate devices do not raise different questions of safety and effectiveness.

Non-Clinical Data

Pull-out testing was performed to verify the fixation properties of the OSSIOfiber® Compression Screw, 3.5mm, and to compare them to those of the metal predicate device (K133842). Testing was done initially and following in-vitro degradation. Torsional testing and rationale were also provided to support the torsional strength and driving torque at time zero for the OSSIOfiber® Compression Screw, 3.5mm.

In vitro degradation and biocompatibility for the implants were established based on the cleared primary predicate device (K193660) and referenced device (K203465). A rationale was provided to support the MR safe labeling of the device.

Conclusions

The OSSIOfiber® Compression Screw, 3.5mm is as safe and effective as its predicate devices. The OSSIOfiber® Compression Screws, 3.5mm have the same intended use, indications for use, material composition, manufacturing and sterilization methods and principles of operation as the primary predicate device (K193660). The minor design differences and additional lengths do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. Non-clinical pull-out testing data and torsional rationales demonstrate that the OSSIOfiber® Compression Screw, 3.5mm is at least as safe and effective as its predicates (K193660, K133842). Thus, the OSSIOfiber® Compression Screws, 3.5mm are substantially equivalent to its predicate devices.