December 23, 2022

OSSIO Ltd.
% David Mcgurl
Director, Regulatory Affairs
Mcra, LLC
803 7th Street North West, Floor 3
Washington, District of Columbia 20001

Re: K221193
Trade/Device Name: OSSIOfiber Compression Screw, OSSIOfiber Compression Screw, 6.5mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 30, 2022
Received: November 30, 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,

Shumaya Ali -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221193

Device Name

OSSIO*fiber*® Compression Screw

Indications for Use *(Describe)*

OSSIO*fiber*® 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.

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

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510(k) SUMMARY

OSSIO*fiber*® Compression Screw, 6.5mm

Submitter

Ossio Ltd.

8 HaTochen Street, Caesarea, Israel, 3079861
Phone: +972-4-9986600
Facsimile: +972-4-9986601
Contact Person: Taly Lindner

Date Prepared: November 30, 2022

Name of Device: OSSIO*fiber*® Compression Screw, 6.5mm
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

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

Reference Devices

Inion CompressOn™ Screw (K203105)
OSSIO*fiber*® Compression Screw (K213596)

Purpose of Submission

This traditional 510(k) premarket notification is being submitted to obtain clearance for a line extension, made from the same material of longer lengths, outside the previously cleared range of the OSSIO*fiber*® Compression Screw family (named OSSIO*fiber*® Compression Screw, 6.5mm).

Device Description

The OSSIO*fiber*® 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 from 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*® 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: 65 - 100 mm long, and 6.5 mm diameter.

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

Indications for Use

OSSIO*fiber*® 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 OSSIO*fiber*® Compression Screws have the same intended use, indications for use, material composition, design characteristics, manufacturing and sterilization methods and principles of operation as the predicate device (K193660). The additional lengths of the OSSIO*fiber*® Compression Screws, 6.5mm do not introduce a new performance worst-case relative to the cleared primary predicate. The additional longer lengths of the subject device are similar to those of the Inion CompressOn™ Screw (K203105) which is cleared for similar indications with similar principles of operation and technological characteristics. Additional chemical characterization testing has been completed, and together with a toxicological risk assessment support these additional lengths. Thus, any differences between OSSIO*fiber*® Compression Screws, 6.5mm and its predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Data

Additional chemical characterization testing has been completed, and together with a toxicological risk assessment support the subject longer screw lengths. Additional mechanical performance testing was not performed as the subject lengths do not present a new worst case for the OSSIO*fiber*® Compression Screw family.

Conclusions

The OSSIO*fiber*® Compression Screws have the same intended use, indications for use, material composition, design characteristics, manufacturing and sterilization methods and principles of operation as the predicate device (K193660). The additional lengths do not alter the intended surgical use of the device and does not affect its safety and effectiveness when used as labeled. The additional lengths vs the predicate device raises no new issues of safety or effectiveness as supported by the chemical characterization data and toxicological risk assessment. The OSSIO*fiber*® Compression Screws is as safe and effective as its predicate device. Thus, the OSSIO*fiber*® Compression Screws is substantially equivalent to the predicate device.