July 30, 2020

Ossio Ltd.
% David McGurl
Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K193660
Trade/Device Name: OSSIOfiber™ Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 30, 2020
Received: June 30, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193660

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.

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510(k) SUMMARY

OSSIO*fiber*™ Compression Screw

Submitter

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

Date Prepared: July 28, 2020

Name of Device: OSSIO*fiber*™ Compression Screw

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

Inion FreedomScrew™ (K123672) – **Primary Predicate**

DePuy Synthes 3.5 mm Cannulated Screw (K161616)

Arthrex Bio-compression Screw (K060478)

Reference Devices

OSSIO™ Pin Product Family (K181180)

OSSIO*fiber*™ Hammertoe Fixation Implant (K190652)

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, and are available in several sizes: 26-60 mm long, and 3.5-6.5 mm diameter. The screws are partially threaded, cannulated design.

The OSSIO*fiber*™ Compression Screws are designed to be used with commonly available orthopedic surgical tools such as ISO 5853/ISO 9714 compatible instrumentations.

Indications for Use

The 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 and principles of operation, similar indications for use, design characteristic, and material composition, as the predicate device Inion FreedomScrew™ (K123672). Both the device and the predicate are supplied sterile. The OSSIO*fiber*™ Compression Screw is sterilized by EtO whereas the predicate is sterilized by Gamma. Both device and predicate are degradable. The polymer material of the OSSIO*fiber*™ Compression Screw is the same as the polymeric material of the previously cleared primary predicate. The device also contains continuous mineral fibers whereas the predicate is only polymeric material. The OSSIO*fiber*™ Compression Screws and predicate are available in similar design and sizes, where the subject device includes larger diameters and a slightly more limited set of screw designs than the predicate device. Although there are differences with regards to shape and size as compared to the predicate, mechanical testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIO*fiber*™ Compression Screw and its predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Data

Mechanical testing of pull-out and flexural bending was performed to verify the fixation and strength properties of the OSSIO*fiber*™ Compression Screw, and to compare them to those of the predicate device (K123672). Pull out properties were also compared to those of the metal referenced device (K161616). Testing was done initially and following in-vitro degradation. Torsional strength and driving torque at time zero were also conducted for the OSSIO*fiber*™ Compression Screw.

Biocompatibility for the implants was established primarily based on the referenced ISO 10993 data from the previously cleared reference devices (K181180, K190652) as well as a rationale. A rationale was provided to support the MR safe labeling of the device.

Conclusions

The OSSIO*fiber*™ Compression Screw is as safe and effective as its predicate device, Inion FreedomScrew™ (K123672). The OSSIO*fiber*™ Compression Screws have the same intended use and principles of operation, similar indications for use, design characteristic, and material composition, as the predicate device Inion FreedomScrew™ (K123672). The minor differences do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. Non-clinical testing data demonstrate that the OSSIO*fiber*™ Compression Screw is at least as safe and effective as the predicate device. Thus, the OSSIO*fiber*™ Compression Screw is substantially equivalent.