September 13, 2023

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

Re: K230750
Trade/Device Name: OSSIOfiber® Cannulated Trimmable Fixation Nail
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: August 16, 2023
Received: August 16, 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 (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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K230750

Device Name
OSSIOfiber® Cannulated Trimmable Fixation Nail

Indications for Use *(Describe)*
OSSIOfiber® Cannulated Trimmable Fixation Nails are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis, and bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

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® Cannulated Trimmable Fixation Nail

Submitter

Ossio Ltd.

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Contact Person: Taly Lindner

Date Prepared: March 17, 2023

Name of Device: OSSIOfiber® Cannulated Trimmable Fixation Nail

Common or Usual Name: fixation, pin, smooth

Classification Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II, 21 C.F.R. § 888.3040

Product Code: HTY

Predicate Devices

OSSIOfiber® Cannulated Trimmable Fixation Nail (K203465)

Reference Devices

- Arthrex Bio-pin (K050259)
- OSSIOfiber® Compression Screw, 6.5mm (K221193)
- OSSIO® Pin Product Family (K181180)

Purpose of Submission

This traditional 510(k) premarket notification is submitted to obtain clearance for an additional device having the same design characteristics, made of the same material, but longer and outside the previously cleared range of the OSSIOfiber® Cannulated Trimmable Fixation Nail family (K203465).

Device Description

The OSSIOfiber® Cannulated Trimmable Fixation Nails are fixation devices 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 materials 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® Cannulated Trimmable Fixation Nails are cannulated, supplied sterile, for single patient use only, and non-pyrogenic. The additional device included in this submission is 100 mm long and 3.5mm core diameter (4.0 mm outer diameter).

The OSSIOfiber® Cannulated Trimmable Fixation Nails are designed to be used with commonly available orthopedic surgical tools such as ISO 9714 compatible instrumentations.

Indications for Use

OSSIOfiber® Cannulated Trimmable Fixation Nails are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis, and bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Summary of Technological Characteristics

The OSSIOfiber® Cannulated Trimmable Fixation Nails have the same intended use, indications for use, material composition, design characteristics, manufacturing and sterilization methods and principles of operation as the predicate device (K203465). The additional length of the OSSIOfiber® Cannulated Trimmable Fixation Nail, does not introduce a new performance worst-case relative to the cleared predicate. The longer length of the subject device is similar to the Arthrex Bio-pin device (K050259) which is cleared for similar indications with similar principles of operation and design characteristics. The longer length of the subject device is also similar to the longest OSSIOfiber® Compression Screw, 6.5mm (K221193) which is made of the same material composition and is cleared for similar indications with similar principles of operation and design characteristics.

Both the device and the predicate are supplied sterile and sterilized by EtO.

Non-Clinical Data

Non-clinical performance testing was not performed as the subject device does not represent a new mechanical performance worst-case for the OSSIOfiber® Cannulated Trimmable Fixation Nail cleared family. The technological characteristics of the subject device vs the predicate device remain identical aside from the longer length.

Biocompatibility for the implants was established primarily based on the referenced ISO 10993 data from the previously cleared predicate (K203465) and reference devices (K181180, K221193) as well as a rationale. The MR safe labeling of the device was established based on the cleared predicate device's labeling.

Conclusions

The OSSIOfiber® Cannulated Trimmable Fixation Nails have the same intended use, indications for use, material composition, principles of operation, and design characteristics as the predicate device (K203465). The additional length of the OSSIOfiber® Cannulated Trimmable Fixation Nail, does not alter the intended surgical use of the device and does not affect its safety and effectiveness when used as labeled. The additional length does not represent a new worst-case for the OSSIOfiber® Cannulated Trimmable Fixation Nail family and does not raise new issues of safety or effectiveness. Thus, the OSSIOfiber® Cannulated Trimmable Fixation Nail is substantially equivalent to the predicate device.