January 6, 2021

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

Re: K203465
Trade/Device Name: OSSIOfiber Cannulated Trimmable Fixation Nail, OSSIOfiber Trimmable Fixation Nail, OSSIOfiber Trimmable Fixation Nail, Cannulated Design
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: November 24, 2020
Received: November 24, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203465

Device Name

OSSIOfiber® Cannulated Trimmable Fixation Nail, OSSIOfiber® Trimmable Fixation Nail, OSSIOfiber® Trimmable Fixation Nail, Cannulated Design

Indications for Use *(Describe)*

OSSIOfiber® 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® Trimmable Fixation Nail, Cannulated Design

Submitter

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Contact Person: Taly Lindner

Date Prepared: November 24, 2020

Name of Device: OSSIOfiber® Cannulated Trimmable Fixation Nail, OSSIOfiber® Trimmable Fixation Nail, OSSIOfiber® Trimmable Fixation Nail, Cannulated Design

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

Primary Predicate Device

OSSIO® Pin Product Family (K181180)

Reference Devices

OSSIOfiber® Hammertoe Fixation System (K190652)

OSSIOfiber® Compression Screw (K193660)

Device Description

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).

The OSSIOfiber® Cannulated Trimmable Fixation Nail is a fixation device 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. They are available in several sizes: 10-70 mm long, and 2.80-4.60 mm nominal diameter (core diameter of 2.4-4.00 mm).

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® 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, and principles of operation, and similar design characteristics as the predicate device OSSIO® Pin Product Family (K181180) and the reference device OSSIOfiber® Hammertoe Fixation System (K190652).

The OSSIOfiber® Cannulated Trimmable Fixation Nails' material as well as the manufacturing methods are the same as that of the cleared predicate device OSSIO® Pin Product Family (K181180). Both the device and the predicate are supplied sterile, both sterilized by EtO. Although there are differences with regards to shape and size and cannulation as compared to the predicate, mechanical testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIOfiber® Cannulated Trimmable Fixation Nail and its predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Data

Flexural bending, pull-out, and shear testing were performed to verify the strength and fixation properties of the OSSIOfiber® Cannulated Trimmable Fixation Nail, and to compare them to those of the predicate device (K181180). Testing was done initially and following in-vitro degradation. The in-vitro degradation profile (i.e., change in material properties) was characterized.

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

Conclusions

The OSSIOfiber® Cannulated Trimmable Fixation Nail is substantially equivalent to its predicate device, OSSIO® Pin Product Family (K181180). The OSSIOfiber® Cannulated Trimmable Fixation Nails have the same intended use, indications for use, material composition, and principles of operation, and similar design characteristics as the predicate device OSSIO® Pin Product Family (K181180) and the reference device OSSIOfiber® Hammertoe Fixation System (K190652). The minor differences do not alter the intended surgical use of the device and do not affect its substantial equivalence when used as labeled. Non-clinical testing data demonstrate that the OSSIOfiber® Cannulated Trimmable Fixation Nail has a substantially equivalent safety and effectiveness profile as the predicate device. Thus, the OSSIOfiber® Cannulated Trimmable Fixation Nail is substantially equivalent.