March 6, 2020

Ossio Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K190652
Trade/Device Name: OSSIO*fiber*™ Hammertoe Fixation System/OSSIO*fiber*™ Hammertoe Fixation Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: February 25, 2020
Received: February 25, 2020

Dear Janice Hogan:

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,

for

Ronald P. Jean, Ph.D.
Director (Acting)
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)*

K190652

Device Name

OSSIO*fiber*™ Hammertoe Fixation System/ OSSIO*fiber*™ Hammertoe Fixation Implant

Indications for Use *(Describe)*

The OSSIO*fiber*™ Hammertoe Fixation System/ OSSIO*fiber*™ Hammertoe Fixation Implant is 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

OSSIO*fiber*™ Hammertoe Fixation System

Submitter

Ossio Ltd.

8 HaTochen Street, Caesarea, Israel, 3079861

Phone: +972-4-9986600
Facsimile: +972-4-9986601

Contact Person: Taly Lindner

Date Prepared: March 13, 2019

Name of Device: OSSIO*fiber*™ Hammertoe Fixation System/
OSSIO*fiber*™ Hammertoe Fixation Implant

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 Devices

OSSIO™ Pin Product Family (K181180)

Reference Devices

Arthrex PIP Dart (K141577)

Device Description

The OSSIO*fiber™* Hammertoe Fixation Systems\OSSIO*fiber™* Hammertoe Fixation Implants include implants that have a ribbed design that is inserted between the proximal and middle phalanges, so the ribs fixate on the phalangeal canal of the toe. The OSSIO*fiber*™ Hammertoe fixation implants are made of OSSIO*fiber™* material which is 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*™ Hammertoe Fixation Implants are supplied sterile, pre-mounted on an implant inserter, offered in straight and 10-degree variations, and are available in several sizes: 16-21 mm long and 2.5-3.2 mm nominal diameter.

The OSSIO*fiber*™ Hammertoe Fixation System is a sterile kit which includes in addition to the implant pre-mounted on an inserter, a drill bit and a k-wire which are the instrumentations required for the procedure.

Indications for Use

The OSSIO*fiber™* Hammertoe Fixation System\OSSIO*fiber™* Hammertoe Fixation Implant is 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 OSSIO*fiber™* Hammertoe Fixation System has the same intended use, indications for use and material composition, and very similar design characteristic and principles of operation as the predicate device OSSIO™ Pin Product Family (K181180). The OSSIO*fiber™* Hammertoe Fixation System's biocomposite material as well as the manufacturing techniques are the same as that of the cleared predicate. Both the device and the predicate are supplied sterile and are sterilized by EtO. Although there are differences in 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™* Hammertoe Fixation System and its predicate device do not raise different questions of safety and effectiveness.

Performance Data

Mechanical testing of flexural bending, shear and pull-out was performed to verify the strength and fixation properties of the OSSIO*fiber™* Hammertoe Fixation System, and to compare them to those of the predicate device. Testing was conducted initially and after in vitro degradation.

In vitro degradation testing was carried out to determine the degradation profile (i.e., change in material and mechanical properties) and verify the sufficiency of the mechanical stability over the 12-week healing period. Testing included weight loss, decrease in molecular weight, flexural strength testing, shear strength testing, and pullout testing over 12 weeks.

Material biocompatibility for the implants and instruments was primarily established by use of material identical to the predicate or use of well-established material. Additional testing consisting of cytotoxicity and pyrogenicity (LAL) testing was performed on final, finished products. A rationale was provided to support the MR safe labeling of the device.

Stainless steel instruments were tested for resistance to corrosion and met the relevant acceptance criteria.

Conclusions

The OSSIO*fiber*™ Hammertoe Fixation System and OSSIO*fiber*™ Hammertoe Fixation Implant is substantially equivalent to its predicate device, OSSIO™ Pin Product Family (K181180). The OSSIO*fiber*™ Hammertoe Fixation Implant has the same intended uses, indications of use and material composition and similar technological characteristics and principles of operation as its predicate device. 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*™ Hammertoe Fixation System is substantially equivalent to the predicate device. Thus, the OSSIO*fiber*™ Hammertoe Fixation System is substantially equivalent.