October 16, 2020

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

Re: K201803
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: September 17, 2020
Received: September 17, 2020

Dear Ms. 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 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)*

K201803

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.**

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**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: June 30, 2020

**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

**Predicate Devices**

OSSIO*fiber*™ Hammertoe Fixation System (K190652)

**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. OSSIO*fiber*™ implants have been shown to be biocompatible. 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, material composition, design characteristic and principles of operation as the predicate device (K190652). There have been no changes to the device and the technological characteristics remain identical. Additional chemical characterization has been completed, and together with a toxicological risk assessment provide the basis for the labeling revision.

**Conclusions**

The OSSIO*fiber*™ Hammertoe Fixation System has the same intended uses, indications of use, material composition technological characteristics and principles of operation as its predicate device (K190652). The labeling change does not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. Chemical characterization data support the labeling revision. Therefore, the OSSIO*fiber*™ Hammertoe Fixation System is substantially equivalent to its predicate device.