January 10, 2019

Ossio Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K181180
Trade/Device Name: OSSIO™ Pin Product Family
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: December 3, 2018
Received: December 3, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181180

Device Name
OSSIO™ Pin Product Family

Indications for Use *(Describe)*
The OSSIO™ Pin Product Family 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™ Pin Product Family

Submitter

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Date Prepared: Jan 9, 2019

Name of Device: OSSIO™ Pin Product Family
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

Inion OTPS™ Biodegradable Pin (K050275)

Reference Devices

Inion FreedomPin™, (K133932)
BonAlive Biomaterials Ltd., BonAlive® granules, (K071199)
Depuy Mitek, Milagro/Milagro Advance Interference Screw (K143660)

Device Description

The OSSIO™ Pin Product Family 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 mineral fibers are made from materials that are incorporated into bone.

The OSSIO™ Pin Product Family implants are supplied sterile and are available in several sizes: 10-70 mm long and 2-4 mm nominal dimension, and with a circular, hexagonal or octagonal cross-sectional design.

Indications for Use

The OSSIO™ Pin Product Family 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™ Pin Product Family has the same intended use and indications for use, and very similar principles of operation and design characteristics as the predicate device Inion OTPS™ Biodegradable Pin (K050275). The OSSIO™ Pin's biocomposite material is a combination of previously cleared materials for bone implantation applications with a history of safe clinical use. The polymeric

component of the OSSIO™ Pin is similar to its cleared predicate and is the same as the polymeric material of the previously cleared Inion FreedomPin™ (K133932). This polymeric component is reinforced with minerals, whose material is similar to previously cleared bone void filler devices (e.g., K071199). Several biocomposite orthopedic implants, each comprised of polymeric material together with a mineral composition of a bone void filler material, have previously been FDA-cleared (e.g., K143660) for implantation in bone. Although there are differences with regard 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™ Pin and its predicate device do not raise different questions of safety and effectiveness.

Performance Data

Mechanical testing of flexural bending, shear and pull-out testing was performed to verify the strength and fixation properties of the OSSIO™ Pin, 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 chemical and mechanical properties) and verify the sufficiency of the mechanical stability over the healing period.
Performance over time was also assessed via an in-vivo preclinical study vs a metal k-wire.

The biocompatibility evaluation for the OSSIO™ Pin was conducted in accordance with ISO 10993, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process (2009) and the FDA Guidance "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" (2016).

The battery of testing included the following tests:
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- In-Bone Implantation
- Subacute and Chronic Systemic Toxicity

A Biological Compatibility (Toxicological) Risk Assessment was conducted based on the above test results.

Biocompatibility testing, including an in-bone implantation versus the predicate device to 104 weeks was completed to show that no new issues of safety and effectiveness arise due to the minor material compositional changes.

A rationale was provided in addition to electrical resistivity testing to support the MR safe labeling of the device.

Conclusions

The OSSIO™ Pin Product Family is as safe and effective as its predicate device, Inion OTPS™ Biodegradable Pin (K050275). The OSSIO™ Pin Product Family has the same intended use and indications for use, and substantially similar principles of operation and technological characteristics, as its predicate device. The minor technological differences between the OSSIO™ Pin Product Family and its predicate device raise no new issues of safety or effectiveness. Non-clinical testing data demonstrate that the OSSIO™ Pin is as safe and effective as the predicate device. Thus, the OSSIO™ Pin Product Family is substantially equivalent.