



December 1, 2023

OSSIO Ltd.
% Taly Linder
Vice President, Scientific & Regulatory Affairs
Ossio, Ltd
8 HaTochen St.
Caesarea, 3079861 ISR

Re: K231272

Trade/Device Name: OSSIOfiber® Pin Product Family, OSSIOfiber® Compression Screw,
OSSIOfiber® 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, HWC

Dated: November 1, 2023

Received: November 1, 2023

Dear Taly Linder:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

510(k) Number (if known)
K231272

Device Name

OSSIOfiber® Compression Screw

Indications for Use (Describe)

OSSIOfiber® Compression Screws are indicated for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis, and bone grafts, of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

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.

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Indications for Use

510(k) Number (if known)

K231272

Device Name

OSSIOfiber® Trimmable Fixation Nails

Indications for Use (Describe)

The 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) in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

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)

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510(k) Number (*if known*)
K231272

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) in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

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)

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510(k) SUMMARY

OSSIO® Pin Product Family, OSSIOfiber® Compression Screw, OSSIOfiber® Trimmable Fixation Nail

Submitter

Ossio Ltd.

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Contact Person: Taly Lindner

Date Prepared: Dec 1, 2023

Devices

- **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: OSSIO® Pin Product Family (K181180) – **Primary Predicate**
- **Name of Device:** OSSIOfiber® Compression Screw
Common or Usual Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II, 21 C.F.R. § 888.3040
Product Code: HWC
Predicate: OSSIOfiber® Compression Screw (K193660, K213596, K221193) – Additional Predicate
DePuy Synthes Screws (K161616) – Additional Predicate
- **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
Predicate: OSSIOfiber® Cannulated Trimmable Fixation Nail,
OSSIOfiber® Trimmable Fixation Nail,
OSSIOfiber® Trimmable Fixation Nail, Cannulated Design
(K203465, K230750) – Additional Predicate

Purpose of Submission

This traditional 510(k) premarket notification is being submitted to obtain pediatric indications, i.e., children (2-12 years) and adolescents (12-21 years), for OSSIO's devices previously cleared under K181180, K193660, K213596, K221193, K203465, and K230750.

Device Description

The OSSIOfiber® devices are 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 minerals 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.

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) in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

OSSIOfiber® Compression Screws are indicated for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis, and bone grafts, of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

The 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) in adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

Summary of Technological Characteristics

The OSSIOfiber® subject devices have identical intended use, material composition, design characteristics, manufacturing and sterilization methods and principles of operation, and similar indications for use as their predicate devices (K181180, K193660, K213596, K221193, K203465, K230750). All devices are available in sizes appropriate for the children and adolescents patient population. The OSSIOfiber® subject devices have similar indications for use including the children and adolescents patient population, and similar design characteristics as the additional predicate device (K161616).

Thus, any differences between the subject devices and their predicates do not raise different questions of safety and effectiveness.

Non-Clinical Data

Toxicological risk assessment and chemical characterization data support the addition of the children and adolescents patient population to the indications for use. Additional mechanical

performance testing was not performed as the indications for use of the subject devices do not present a new worst case compared to the cleared OSSIOfiber® predicates.

Conclusions

The OSSIOfiber® subject devices have identical intended use, material composition, design characteristics, manufacturing and sterilization methods and principles of operation, and similar indications for use as their predicate devices (K181180, K193660, K213596, K221193, K203465, K230750). The addition of children and adolescents patients to the indications for use raises no new issues of safety or effectiveness, as supported by the chemical characterization data and toxicological risk assessment. All devices are available in sizes appropriate for the children and adolescents patient population. The OSSIOfiber® subject devices have similar indications for use including the children and adolescents patient population, and similar design characteristics as the additional predicate device (K161616). The addition of children and adolescents patients to the indications for use does not affect safety and effectiveness when used as labeled. Thus, the OSSIO® Pin Product Family, OSSIOfiber® Compression Screw, OSSIOfiber® Trimmable Fixation Nail, are substantially equivalent to their predicate devices.