March 28, 2022

OSSIO Ltd.
% David McGurl
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K213415
Trade/Device Name: OSSIOfiber® Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: March 1, 2022
Received: March 1, 2022

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213415

Device Name

OSSIOfiber® Suture Anchor

Indications for Use *(Describe)*

The OSSIOfiber® Suture Anchors are indicated for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.
- Knee: Anterior Cruciate Ligament Repair (4.75-5.5 Anchors Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis and Quadriceps Tendon Repair. Secondary or adjunct fixation of ACL/PCL reconstruction or repair (4.75 – 5.5 Anchors only).
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair (Tennis Elbow).

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.

510(k) SUMMARY

OSSIOfiber® Suture Anchor

Submitter

Ossio Ltd.

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Contact Person: Taly Lindner
Date Prepared: March 01, 2022

Name of Device: OSSIOfiber® Suture Anchor

Common or Usual Name: Fastener, Fixation, Biodegradable, Soft Tissue

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II, 21 C.F.R. § 888.3030

Product Code: MAI

Predicate Devices

Arthrex SwiveLock Suture Anchor (K193503) – **Primary Predicate**

Reference Devices

OSSIO® Pin Product Family (K181180)
OSSIOfiber® Hammertoe Fixation System (K190652, K201803)
OSSIOfiber® Compression Screw (K193660)
OSSIOfiber® Cannulated Trimmable Fixation Nail (K203465)

Device Description

The OSSIOfiber® Suture Anchor consists of an eyelet and anchor body preloaded on an inserter. The anchor body and eyelet are made from poly (L-lactide-co-D,L-lactide) (PLDLA) reinforced with continuous mineral fibers. OSSIOfiber® 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 OSSIOfiber® implants degrade, the load transfers to the surrounding anatomy throughout the healing period of the bone. Substantial degradation takes place within approximately 18 months as shown in pre-clinical studies, thus eliminating the requirement for future hardware removal surgery. Sutures, needles and suture snare may also be provided with the device depending on configuration.

The OSSIOfiber® Suture Anchors are sterile, single-use, and non-pyrogenic.

Indications for Use

The OSSIO*fiber*® Suture Anchors are indicated for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.
- Knee: Anterior Cruciate Ligament Repair (4.75-5.5 Anchors Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis and Quadriceps Tendon Repair. Secondary or adjunct fixation of ACL/PCL reconstruction or repair (4.75 – 5.5 Anchors only).
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair (Tennis Elbow).

Summary of Technological Characteristics

The OSSIOfiber® Suture Anchor has the same intended use, indications for use, and principles of operation, and similar material composition and design characteristics as the predicate device Arthrex SwiveLock Suture Anchor (K193503).

The material and manufacturing methods of the OSSIOfiber® anchor and eyelet are the same as that of the cleared reference devices (K181180, K190652, K201803, K193660, K203465). Sutures with or without needles are assembled with the anchor and eyelet on an inserter and sterilized with EtO.

Both the device and the predicate are supplied sterile, both sterilized by EtO. Although there are slight design (e.g. length, diameters) and material differences compared to the predicate, mechanical testing demonstrated at least equivalent performance both initially and after in vitro degradation. Any differences between OSSIOfiber® Suture Anchor and its predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Data

Static pull-out and cyclic pull-out testing were performed to verify the strength and fixation properties of the OSSIOfiber® Suture Anchor, and to compare them to those of the predicate device (K193503). Testing was done initially and following in-vitro degradation. The in-vitro degradation profile was characterized. Torsional strength, driving torque, and insertion testing at time zero were also conducted for the OSSIOfiber® Suture Anchor.

Biocompatibility for the device was primarily established by use of material identical to the reference devices or use of well-established material. Biocompatibility for the implants (Anchor and Eyelet) was established primarily based on the referenced ISO 10993 data from the previously cleared reference

devices (K181180, K190652, K201803). Biocompatibility for the sutures and needles was established within their 510(k) clearances.
Biocompatibility testing for the inserter included cytotoxicity, endotoxin pyrogenicity testing, material mediated pyrogenicity testing, irritation, acute systemic toxicity and sensitization testing.

A rationale was provided to support the MR safe labeling of the device.

Conclusions

The OSSIOfiber® Suture Anchor is as safe and effective as its predicate device, Arthrex SwiveLock Suture Anchor (K193503). The OSSIOfiber® Suture Anchors have the same intended use, indications for use, and principles of operation, and similar material composition and design characteristics as the predicate device Arthrex SwiveLock Suture Anchor (K193503). 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 OSSIOfiber® Suture Anchor is at least as safe and effective as the predicate device. Thus, the OSSIOfiber® Suture Anchor is substantially equivalent.