July 3, 2019

Oxford Performance Materials, Inc.
Mr. Andrus Maandi
Product Development Engineer
30 South Satellite Road
South Windsor, Connecticut 06074

Re: K190915
Trade/Device Name: OsteoFab® Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 8, 2019
Received: April 9, 2019

Dear Mr. Maandi:

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 Laurence Coyne, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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)*

K190915

Device Name
OsteoFab® Suture Anchors

Indications for Use *(Describe)*
The OsteoFab® Suture Anchors are intended to be used for the fixation/reattachment of soft tissue to bone in the shoulder, knee, hand and wrist, elbow, and foot and ankle 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, Anterior Shoulder Instability Repair.

Knee: Extra Capsular Ligament Repair, Patellar Realignment and Tendon Repairs, and Illiotibial Band Tenodesis.

Hand and Wrist: Ulnar or Lateral Collateral Ligament Reconstruction, Collateral Ligament Reconstruction or Repair.

Elbow: Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair, Biceps Tendon Repair.

Foot and Ankle: Hallux Valgus Repairs, Medial or Lateral Instability Repairs and Reconstructions, Achilles Tendon Repairs and Reconstructions, Midfoot Reconstructions, Metatarsal Ligament/Tendon Repairs and Reconstructions, Bunionectomy.

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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005 – 510(k) Summary [As required by 21 CFR 807.92]

I. Submitter

510(k) Owner:	Oxford Performance Materials, Inc. 30 South Satellite Road South Windsor, CT 06074 USA Phone: (860)-698-9300 Fax: (860)-698-9978
Submitter/Contact:	Andrus Maandi Product Development Engineer Oxford Performance Materials, Inc. 30 South Satellite Road South Windsor, CT 06074 USA Phone: (860)-656-9437
Date Prepared:	April 17, 2019

II. Device

Proprietary Name:	OsteoFab® Suture Anchors
Common or Usual Name:	Bone anchors, suture anchors
Classification:	21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener
Regulatory Class:	Class II
Product Code:	MBI
Review Panel:	Orthopedic

III. Predicate Device

Predicate Device:	K122314 Cayenne Quattro Link Knotless Anchors

IV. Device Description

The OsteoFab® Suture Anchor is a single procedure suture anchor device for the reattachment of soft tissue to bone in shoulder, knee, hand and wrist, elbow, and foot and ankle procedures. This reattachment of damaged soft tissue is achieved with suture that is threaded through an anchor which is fixated in bone via interference fit between the anchor and bone. The anchor is mounted on a custom inserter and threaded with recommended suture before deployment. The OsteoFab® Suture Anchors are manufactured from polyetherketoneketone (PEKK) polymer in Oxford Performance Materials, Inc.'s proprietary additive manufacturing process. The OsteoFab® Suture Anchors are available in three sizes (4.5, 5.5, ad 6.5mm) and are provided non-sterile.

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Intended Use Statement

The OsteoFab® Suture Anchors are intended to be used for the fixation/reattachment of soft tissue to bone in the shoulder, knee, hand and wrist, elbow, and foot and ankle 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, Anterior Shoulder Instability Repair.

Knee: Extra Capsular Ligament Repair, Patellar Realignment and Tendon Repairs, and Illiotibial Band Tenodesis.

Hand and Wrist: Ulnar or Lateral Collateral Ligament Reconstruction, Collateral Ligament Reconstruction or Repair.

Elbow: Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair, Biceps Tendon Repair.

Foot and Ankle: Hallux Valgus Repairs, Medial or Lateral Instability Repairs and Reconstructions, Achilles Tendon Repairs and Reconstructions, Midfoot Reconstructions, Metatarsal Ligament/Tendon Repairs and Reconstructions, Bunionectomy.

V. Comparison of Technological Characteristics with the Predicate Device

Principle of Operation

The basic operational principle of the OsteoFab® Suture Anchors is the same as the predicate: the operating principle of the OsteoFab® Suture Anchors is to fixate/reattach soft tissue to bone.

Technological Characteristics

The technological characteristics of the OsteoFab® Suture Anchor devices are similar to the predicate device in terms of operating principle and intended use. The OsteoFab® Suture Anchors are deployed into a pilot hole using a custom inserter and recommended suture in order to secure soft tissue to bone. Any differences in technological characteristics are summarized below:

- Design: optimized design for additive manufacturing with same general characteristics to achieve a secure interference fit in bone.
- Material: polyetherketoneketone (PEKK) is used instead of polyetheretherketone (PEEK).
- Manufacturing method: OsteoFab® Suture Anchors are manufactured in an additive process compared to conventional machining.

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VI. Performance Data

For determination of substantial equivalence, insertion testing, pullout testing, and fatigue testing were performed. Mechanical testing showed that the mechanical strength and function of the subject device is substantially equivalent to the legally marketed predicate device and that it is sufficient for the intended use. A biological safety assessment was also performed that demonstrated that the subject device is biocompatible for long term implantation and substantially equivalent to the legally marketed predicate device.

Performance Bench Testing

The following performance bench tests were completed:

- Insertion testing
- Static pullout testing
- Fatigue testing

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence.

Biocompatibility Testing

A biological safety assessment was performed that evaluated endpoints including cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, genotoxicity, implantation, chronic toxicity, and carcinogenicity. Endotoxin testing was also performed.

Sterilization and Cleaning

Sterilization and cleaning instructions in the subject device labeling are provided per validated methods and parameters.

VII. Substantial Equivalence Conclusion

This submission supports the position that the subject implants are substantially equivalent to the previously cleared predicate devices. The subject and predicate devices are similar in terms of indications for use, operating principles, technological characteristics, and mechanical strength. There are no significant differences between the subject and predicate device that would affect the safety and effectiveness of the OsteoFab® Suture Anchors. Any differences were not considered significant based on the data provided in this submission.

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