June 29, 2023

OsteoCentric Technologies
Todd Evans
Senior Director of Quality & Regulatory Affairs
75 West 300 North
Suite 150
Logan, Utah 84321

Re: K230595
Trade/Device Name: OsteoCentric ACL Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 1, 2023
Received: June 8, 2023

Dear Todd Evans:

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,

Jesse Muir -S

Jesse Muir, PhD
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)*
K230595

Device Name
OsteoCentric ACL Fixation System

Indications for Use *(Describe)*
The OsteoCentric ACL Fixation Fasteners are used to provide bone fixation in orthopedic procedures, including bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

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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510(k) Summary

I. Submitter Information

Manufacturer:
OsteoCentric Technologies
75 West 300 N, Suite 150
Logan, UT 84321
Phone: 1-800-969-0639

Contact Person:
Todd Evans, Senior Director of Quality and Regulatory Affairs
OsteoCentric Technologies

II. Device

Device Proprietary Name:	OsteoCentric ACL Fixation Fastener System
Common or Usual Name:	ACL Fastener System
Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number:	21 CFR 888.3040
Product Code:	HWC
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate: ConMed EZStart, Interference Screw, K182955
- Additional Predicate: Arthrex Titanium Interference Screws, K052607

IV. Device Description

The OsteoCentric ACL Fastener System consists of ACL Fixation Fasteners and select single-use and reusable instrumentation to facilitate implantation.
The ACL Fixation Fasteners are threaded titanium interference screws with a tapered tip for easy insertion into bone. The fasteners are cannulated to allow the use of a guidewire to assist with placement of the fastener into the bone tunnel. The fastener is used to maintain the fixation of bone-tendon-bone grafts in orthopedic procedures. The ACL Fixation Fasteners are provided sterile.
ACL Fixation single-use instruments are: a 2.4mm OD stainless steel drill-tipped passing pin, a 1.6mm OD nitinol guidewire, and a stainless-steel graft retractor. The ACL single-use instruments are provided sterile.
ACL Fixation reusable instruments are: a 2.5mm hex driver, and a 3.5mm Hex Driver. The ACL Fixation reusable instruments are provided non-sterile and must be sterilized prior to use.

The OsteoCentric ACL Fixation Fastener System Sterile implants are evaluated to be non-pyrogenic.

V. Indications for Use

The OsteoCentric ACL Fixation Fasteners are Used to provide bone fixation in orthopedic procedures, including bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

VI. Comparison of Technological Characteristics

The subject device and predicate device have the same intended use and technological characteristics. Both interference screws are titanium, tapered tip, and cannulated. Both interference screws are used to maintain fixation of bone-tendon-bone grafts in orthopedic procedures.

VII. Performance Data

The following testing and analysis were performed:
• The Torsional Properties (ASTM F543 Annex A1)
• Driving Torque and Removal Torque (ASTM F543 Annex A2)
• Engineering analysis comparison of theoretical axial pullout
• Axial Pushout

VIII. Conclusion

Test results and analysis provide objective evidence that that the subject device is substantially equivalent to a legally marketed predicate.

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