April 18, 2023

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

Re: K230764
Trade/Device Name: OsteoCentric Integrated Hip Fastener System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDO, KTT
Dated: March 17, 2023
Received: March 20, 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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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.

Submission Number *(if known)*

K230764

Device Name

OsteoCentric Integrated Hip Fastener System

Indications for Use *(Describe)*

The OsteoCentric Integrated Hip Fastener System is indicated for stable and unstable intertrochanteric, subtrochanteric, and basilar neck fractures in which a stable medial buttress can be reconstructed.

The OsteoCentric Integrated Hip Fastener System is indicated for femoral neck fractures including intracapsular, transcervical, and subcapital fractures.

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) #: K230764

510(k) Summary

Prepared on: 2023-04-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	OsteoCentric Technologies
Applicant Address	75 West 300 North Suite 150 Logan UT 84321 United States
Applicant Contact Telephone	1-800-969-0639
Applicant Contact	Mr. Todd Evans
Applicant Contact Email	todd.evans@osteocentric.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OsteoCentric Integrated Hip Fastener System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Device, Fixation, Proximal Femoral, Implant
Regulation Number	888.3030
Product Code	JDO,KTT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210247	OsteoCentric Integrated Hip Fastener System	JDO
K182154	Synthes Femoral Neck System (FNS)	KTT
K062066	Stryker Omega 3	KTT
K953607	Synthes Dynamic Hip Screw (DHS)	JDO

Device Description Summary

21 CFR 807.92(a)(4)

The OsteoCentric Integrated Hip Fastener System is intended for use in internal fixation of intertrochanteric and femoral neck fractures of the proximal femur. The OsteoCentric Integrated Hip Fastener System consists of plates and screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. Integrated Hip Fasteners which are lag screws implanted through the femoral neck and head are offered in Ø11, Ø13, & Ø15mm sizes with lengths ranging from 50 – 140mm in 5mm increments. Hip side plates are offered in 1-hole to 19-hole configurations (48 – 330mm length). 6.0mm support fasteners are offered in 55 – 125mm lengths. 5.2mm shaft fasteners are offered in 28 – 46mm lengths. 3.3mm locking fasteners for the trochanter plate are offered in 16 – 40mm lengths. Compression and attachment screws are also available. Devices are provided non-sterile. All implantable devices are manufactured from stainless steel per ASTM F138.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The OsteoCentric Integrated Hip Fastener System is indicated for stable and unstable intertrochanteric, subtrochanteric, and basilar neck fractures in which a stable medial buttress can be reconstructed.

The OsteoCentric Integrated Hip Fastener System is indicated for femoral neck fractures including

intracapsular, transcervical, and subcapital fractures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The OsteoCentric Integrated Hip Fastener System has the same intended use and substantially similar indications for use as the previously cleared primary predicate device (K210247).

The OsteoCentric Integrated Hip Fastener System has the same intended use as and substantially similar indications for use as the secondary predicate devices (K182154, K062066, K953607).

The proposed indications for use statement does not alter the therapeutic effect or use of the implants. In conclusion, the OsteoCentric Integrated Hip Fastener with updated indications for use statement is substantially equivalent to the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

Design changes to include an 11mm Integrated Hip Fastener and 1 & 2-hole versions (48 & 58mm) of the Side Plate do not introduce a new worst-case condition. The change to the Indications for Use does not change the intended use of the device and does not introduce new indications. The changes to design and indications for use does not change the therapeutic effect or use of the implants.

The OsteoCentric Integrated Hip Fastener System is identical to the primary predicate device with respect to sterilization, manufacturing methods, and material. Design changes include the addition of an 11mm Integrated Hip Fastener, the addition of a 1 & 2-hole versions of the Side Plate (48 & 58mm), and additional barrel angles of the Side Plate (130° - 150°). These design changes do not introduce a new worst-case mechanical condition.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

In conclusion, the OsteoCentric Integrated Hip Fastener with updated indications for use statement is substantially equivalent to the predicate devices.