April 30, 2021

OsteoCentric Technologies d.b.a. OsteoCentric Trauma
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K210247
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: January 28, 2021
Received: January 29, 2021

Dear Nathan Wright:

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,

Christopher Ferreira -S

for

Vesa Vuniqi
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.

510(k) Number *(if known)*
K210247

Device Name
0steoCentric Integrated Hip Fastener System

Indications for Use *(Describe)*
The 0steoCentric Integrated Hip Fastener System is intended to treat stable and unstable intertrochanteric, subtrochanteric, and basilar neck fractures in which a stable medial buttress can be reconstructed.

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

Submitter's Name:	OsteoCentric Trauma
Submitter's Address:	75 West 300 North Suite #150 Logan, UT 84321
Submitter's Telephone:	1-800-969-0639
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	January 28, 2021
Trade or Proprietary Name:	OsteoCentric Integrated Hip Fastener System
Common or Usual Name:	Device, Fixation, Proximal Femoral, Implant
Classification:	Class II per 21 CFR §888.3030
Regulation Name:	Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Product Code:	JDO, KTT
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OsteoCentric Integrated Hip Fastener System is intended for use in internal fixation of femoral neck fractures. The OsteoCentric Integrated Hip Fastener System consist of plates and screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The devices are provided non-sterile. All implantable devices are manufactured from Stainless Steel per ASTM F138.

INDICATIONS FOR USE

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

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of Manufacture

510k Number	Trade or Proprietary or Model Name	Manufacturer	Device Category
K953607	Dynamic Hip Screw	Synthes (USA)	Primary
K923613, K791619	Dynamic Hip Screw	Synthes (USA)	Additional
K914546	Angled Blade Plate	Synthes (USA)	Additional
K193029	Conquest FN	Smith & Nephew, Inc.	Additional
K150818	Versa-Fx Femoral Fixation System, Versa-Fx II Femoral Fixation System, Free-Lock Femoral Fixation System	Zimmer, Inc.	Additional
K000972	Trochanter Stabilization Plate for DHS®	Synthes (USA)	Additional
K120772	NCB Periprosthetic trochanter Plates and Screws	Zimmer GMBH	Additional
K170021	SMV Scientific Cannulated Screws	SMV Scientific	Reference

PERFORMANCE DATA

An engineering analysis was performed to compare the subject plating construct to the predicates. Similar to the predicates, the subject plating/screw construct is also a modular stainless steel bone fixation system with similar interlocking features, plate angulation, plate lengths, plate widths, plate thicknesses, screw sizes and screw lengths. Plate strength and stiffness was compared by evaluating the material properties and moment of inertia at worst-case locations. Screw strength was evaluated and compared to the predicates using the material properties, screw types and sizes. Screw fixation was evaluated and compared to predicates using information about the thread profile. The results of the engineering analysis confirmed that the strength, stiffness and fixation of the OsteoCentric Integrated Hip Fastener System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the OsteoCentric Integrated Hip Fastener System is substantially equivalent to the predicate device.