October 9, 2024

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

Re: K242691
Trade/Device Name: OsteoCentric Technologies Cannulated Fasteners and Nuts
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 5, 2024
Received: September 9, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242691

Device Name

OsteoCentric Technologies Cannulated Fasteners and Nuts

Indications for Use *(Describe)*

The OsteoCentric Cannulated Fasteners and Nuts is indicated for use in bone reconstruction, osteotomy, arthrodesis (joint fusion), and fixation of fractures and ligaments:

The OsteoCentric 2.4mm and 3.0mm Cannulated Screw are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The OsteoCentric 3.5mm Cannulated Screws are intended for the arthrodesis or fixation of fractures and fragments of hand, midfoot, and forefoot bones, extremity osteochondritis dissecans lesions, and for extremity ligament fixation.

The OsteoCentric 4.5mm to 8.0mm Cannulated Screws are intended for fixation of long bone fractures and fragments, long bone osteotomies, femoral neck fractures, slipped capital femoral epiphyses, as an adjunct to treatment with a dynamic hip screw (DHS) in basilar neck fractures, tibial plateau fractures, pediatric femoral neck fractures, intercondylar femur fractures, fixation of the pelvis and pelvic joints, and arthrodesis (e.g., ankle, subtalar).

The OsteoCentric 7.0mm and 8.0mm Cannulated Nut is indicated for reduction and stabilization of fractures or inter-osseous distances (e.g. syndesmosis injuries).

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

Prepared on: 2024-09-06

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	435-757-2253
Applicant Contact	Mr. Todd Evans
Applicant Contact Email	todd.evans@osteocentric.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OsteoCentric Technologies Cannulated Fasteners and Nuts
Common Name	Screw, Fixation, Bone (primary); Washer, Bolt, Nut
Classification Name	Smooth or threaded metallic bone fixation fastener (primary), Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	21 CFR 888.3040 (primary), 888.3030
Product Code(s)	HWC (primary), HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211290	OsteoCentric Technologies Cannulated Fasteners and Nuts	HWC
K151418	Monster Screw System™	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The OsteoCentric Technologies Cannulated Fasteners and Nuts come in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The fasteners are provided non- sterile and are manufactured from Stainless Steel per ASTM F138 or from Titanium per ASTM F136 or F1295. Instrumentation is also provided non-sterile to properly insert the OsteoCentric Technologies Cannulated Fasteners and Nuts. All instrumentation is intended to be reusable, with the exception of the guide wires. Guidewires are provided non-sterile and are intended for single-use only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The OsteoCentric Cannulated Fasteners and Nuts is indicated for use in bone reconstruction, osteotomy, arthrodesis (joint fusion), and fixation of fractures and ligaments:

The OsteoCentric 2.4mm and 3.0mm Cannulated Screw are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The OsteoCentric 3.5mm Cannulated Screws are intended for the arthrodesis or fixation of fractures and fragments of hand, midfoot, and forefoot bones, extremity osteochondritis dissecans lesions, and for extremity ligament fixation.

The OsteoCentric 4.5mm to 8.0mm Cannulated Screws are intended for fixation of long bone fractures and fragments, long bone osteotomies, femoral neck fractures, slipped capital femoral epiphyses, as an adjunct to treatment with a dynamic hip screw (DHS) in basilar neck fractures, tibial plateau fractures, pediatric femoral neck fractures, intercondylar femur fractures, fixation of the pelvis and pelvic joints, and arthrodesis (e.g., ankle, subtalar).

The OsteoCentric 7.0mm and 8.0mm Cannulated Nut is indicated for reduction and stabilization of fractures or inter-osseous distances (e.g. syndesmosis injuries).

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

The OsteoCentric Technologies Cannulated Fasteners and Nuts provide support and stabilization for orthopedic procedures. It is substantially equivalent to the predicate device, OsteoCentric Technologies Cannulated Fasteners and Nuts (510(k) Number K211290), as well as Reference Device, Paragon 28, Inc. Monster Screw System™ (510(k) Number K151418).

Safety and Effectiveness:
The device adheres to the same safety standards and performance characteristics as the predicate. No new safety or effectiveness concerns have been identified.

Indications for Use:
The Indications for Use has been updated to indicate the use of OsteoCentric Cannulated Fasteners and Nuts as deemed appropriate for the size of the device, based on the following applications and what is currently cleared: bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation.

The OsteoCentric Technologies Cannulated Fasteners and Nuts remain safe and effective with the updated indications for use, appropriate for the size of the device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices are physically and technologically identical to the previously cleared predicate device (K211290).

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

The Purpose of this submission is to update the indications for use to indicate the use of OsteoCentric Cannulated Fasteners and Nuts as deemed appropriate for the size of the device, based on the following applications and what is currently cleared: bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation. The Indications for use regarding the Cannulated Nuts have not been updated and is identical to what was previously cleared.

Indications for Use statement is similar to OsteoCentric Technologies Cannulated Fasteners and Nuts cleared under K211290 (Primary Predicate) and Paragon 28, Inc. Monster Screw System™ cleared under K151418 (Reference Device).