August 3, 2021

OsteoCentric Technologies
% Meredith May
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K211290
Trade/Device Name: 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: July 1, 2021
Received: July 6, 2021

Dear Meredith May:

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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 on last page.

510(k) Number *(if known)*
K211290

Device Name
Cannulated Fasteners and Nuts

Indications for Use *(Describe)*

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, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.
The OsteoCentric 3.5mm Cannulated Screws are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodesis of the carpals and phalanges, steochnondritis dissecans, and ligament fixation.
The OsteoCentric 4.5mm Cannulated Screws are intended for fracture fixation of long bones and long bone fragments.
The OsteoCentric 6.5mm to 8.0mm Cannulated Screws are intended for fracture fixation of long bones and long bone 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, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, SI joint disruptions, fixation of pelvis and iliosacral joints, and subtalar arthrodesis.
The OsteoCentric 7.0mm and 8.0mm Cannulated Nut is indicated for fracture fixation where fracture compression is desired, and where insertion of the nut-and-bolt system does not increase the risk of morbidity due to the need for surgical access to both sides of the compressed area. The device may also be used when compression between separate bones is desired (e.g. syndesmosis) as long as there is not increased morbidity associated with the insertion of a nut-and-bolt system, as discussed above.

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.

5. 510(K) SUMMARY

Submitter's Name:	OsteoCentric Technologies
Submitter's Address:	75 West 300 North, Suite #150 Logan, UT 84321
Submitter's Telephone:	1-800-969-0639
Contact Person:	Meredith Lee May MS, RAC Empirical Testing Corp. 719.337.7579 MMay@EmpiricalTech.com
Date Summary was Prepared:	June 9, 2021
Trade or Proprietary Name:	Cannulated Fasteners and Nuts
Common or Usual Name:	Screw, Fixation, Bone (primary) and Washer, Bolt Nut
Device Classification Name	Smooth or threaded metallic bone fixation fastener (primary) and Single/multiple component metallic bone fixation appliances and accessories
Classification:	Class II per 21 CFR §888.3040 (primary) and §888.3030
Product Code:	HWC (primary) and HTN
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OsteoCentric Technologies Cannulated Fasteners and Nuts consists of cannulated screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The screws and nuts are provided non-sterile. The screws and nuts are manufactured from Stainless Steel per ASTM F138 or from Titanium per ASTM F136 or F1295. The purpose of this submission is to modify the indications for use.

INDICATIONS FOR USE

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, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The OsteoCentric 3.5mm Cannulated Screws are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodesis of the carpals and phalanges, steochnondritis dissecans, and ligament fixation.

The OsteoCentric 4.5mm Cannulated Screws are intended for fracture fixation of long bones and long bone fragments.

The OsteoCentric 6.5mm to 8.0mm Cannulated Screws are intended for fracture fixation of long bones and long bone 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, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, SI joint disruptions, fixation of pelvis and iliosacral joints, and subtalar arthrodesis.

The OsteoCentric 7.0mm and 8.0mm Cannulated Nut is indicated for fracture fixation where fracture compression is desired, and where insertion of the nut-and-bolt system does not increase the risk of morbidity due to the need for surgical access to both sides of the compressed area. The device may also be used when compression between separate bones is desired (e.g. syndesmosis) as long as there is not increased morbidity associated with the insertion of a nut-and-bolt system, as discussed above.

TECHNOLOGICAL CHARACTERISTICS

The OsteoCentric Cannulated Fasteners and Nuts are made from stainless steel per ASTM F138 and from titanium per ASTM F136 or F1295. The subject and predicate devices have nearly identical 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
- Principles of operation
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K210754	Cannulated Fasteners and Nuts	OsteoCentric Technologies	Primary
K170021	SMV Scientific Cannulated Screws	SMV Scientific	Additional
K193214	Biomet Cannulated Screw System	Biomet	Additional
K190324	OrthoPediatrics Cannulated Screw System	OrthoPediatrics	Additional

PERFORMANCE DATA

No performance testing was required, as no physical changes were made to the devices, the ranges of sizes are comparable to predicate devices with the same indications, and no additional testing is required for the indications modifications proposed.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Cannulated Fasteners and Nuts is substantially equivalent to the predicate device.