July 28, 2022

OsteoCentric Technologies
% Roshana Ahmed
Sr. Regulatory Specialist
Telos Partners, LLC
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K221332
Trade/Device Name: OsteoCentric Spine MIS Pedicle Fastener System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: May 6, 2022
Received: May 9, 2022

Dear Roshana Ahmed:

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,

for

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 below.

510(k) Number *(if known)*
K221332

Device Name
OsteoCentric Spine MIS Pedicle Fastener System

Indications for Use *(Describe)*
The OsteoCentric Spine MIS Pedicle Fastener System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The OsteoCentric Spine MIS Pedicle Fastener System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the OsteoCentric Spine MIS Pedicle Fastener System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

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

Date Prepared: July 8, 2022

I. Submitter Information

Manufacturer:
OsteoCentric Technologies
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Logan, UT 84321
Phone: 1-800-969-0639

Contact Person:
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OsteoCentric Technologies

Prepared by:
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II. Device

Device Proprietary Name:	OsteoCentric Spine MIS Pedicle Fastener System
Common or Usual Name:	Pedicle Fastener System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	21 CFR 888.3070
Product Code:	NKB
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Altus Spine Pedicle Screw System, K151648, Altus Partners, LLC
- Altus Spine Pedicle Screw System, K132280, Altus Partners, LLC

IV. Device Description

The OsteoCentric Spine MIS Pedicle Fastener System is a posterior fusion spinal fixation system which consists of non-sterile pedicle fasteners (Ø4.5 – Ø8.5, 25 – 180 mm), cannulated pedicle

fasteners (Ø5.5 – Ø8.5, 25 – 100 mm), reduction fasteners, extended tab implants, locking caps, and rods (Ø5.5, 30 – 180 mm). The fasteners are used to attach the system components to the non-cervical spine and allows a surgeon to build an implant construct with the intent to stabilize the operative site during the fusion process.

The implant components are manufactured from titanium alloy (ASTM F136).

V. Indications for Use

The OsteoCentric Spine MIS Pedicle Fastener System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The OsteoCentric Spine MIS Pedicle Fastener System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the OsteoCentric Spine MIS Pedicle Fastener System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

VI. Comparison of Technological Characteristics

The OsteoCentric Spine MIS Pedicle Fastener System's components have been previously cleared under predicate device K151648. The OsteoCentric Spine MIS Pedicle Fastener System's components have identical indications for use, materials, sterilization, and manufacturing methods as the predicate.

VII. Performance Data

The OsteoCentric Spine MIS Pedicle Fastener System's components were previously cleared under predicate K151648. No additional performance data was submitted to

demonstrate the substantial equivalence of the subject device to the predicate.

VIII. Conclusion

The OsteoCentric Spine MIS Pedicle Fastener System's components were previously cleared under predicate K151648. The OsteoCentric Spine MIS Pedicle Fastener System is substantially equivalent to predicate device K151648.