September 16, 2022

Altus Partners, LLC
Rand Baker
QA/RA Manager
1340 Enterprise Drive
West Chester, Pennsylvania 19380

Re: K211027
Trade/Device Name: Altus Spine Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: March 22, 2021
Received: April 6, 2021

Dear Rand Baker:

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: March 16, 2018
See PRA Statement below.

510(k) Number *(if known)*

K211027

Device Name

Altus Spine Pedicle Screw System

Indications for Use *(Describe)*

The Altus Spine Pedicle Screw 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 Altus Spine Pedicle Screw 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.

When used in a posterior percutaneous approach with MIS instrumentation, the Altus Spine Pedicle Screw 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.

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510(k) Summary

SUBMITTER: Altus Partners
1340 Enterprise Drive
West Chester , PA 19380
Phone: 610-356-6148
Fax: 610-300-3049

CONTACT PERSON: Rand Baker
QA/RA Manager
rbaker@altus-spine.com

DATE PREPARED: August 19, 2022

COMMON NAME: Uni-Planar Screw

PROPRIETARY NAME: Altus Spine Pedicle Screw System

PRIMARY PREDICATE DEVICES: Monaco HA Pedicle Screw System (K200922)

ADDITIONAL PREDICATE DEVICES:
Altus Spine Pedicle Screw System (K181339)
Altus Spine Pedicle Screw System (K200322)
Vertebron Pedicle Screw System (K033352)
Zimmer Optima® ZS Spinal Hook System (K071880)
Synthes Click'X® Monoaxial System(K031175)

CLASSIFICATION NAME: 21 CFR §888.3070 Thracolumbosacral Pedicle Screw Spinal System
21 CFR §888.3060 Appliance, Fixation, Spinal Intervertebral Body

PRODUCT CODES: NKB, KWQ

DEVICE CLASS: Class II

MATERIAL: The materials used are Titanium Alloy material that conforms to ASTM F136 and Cobalt Chrome that conforms to ASTM F1537.

DEVICE DESCRIPTION:

The Altus Spine Pedicle Screw System consists of a system of implantable screws to be used with implantable rods for the purpose of aiding in spinal fusion. The Altus Spine Pedicle Screw System attaches to the vertebral body by means of screws to the non-cervical spinal and allows a surgeon to build a spinal implant construct with the intent to stabilize the spinal operative site during the fusion process of bone graft in the disc space. Implantable components are composed of titanium alloy meeting the requirements of ASTM F136 and cobalt chrome meeting the requirements of ASTM F1537. The device is supplied non-sterile and is intended for sterilization by hospital personnel.

INDICATIONS FOR USE:

The Altus Spine Pedicle Screw 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 Altus Spine Pedicle Screw 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.

When used in a posterior percutaneous approach with MIS instrumentation, the Altus Spine Pedicle Screw 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.

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

Dynamic compression bend tests was performed in accordance with ASTM F1717-15. Flexion-extension, torsional grip, and axial grip was preformed in accordance with ASTM F1798-13. Bench tests demonstrated that the Altus Spine Pedicle Screw System is substantially equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The Altus Spine Pedicle Screw System is the same as the primary predicate (K200322) in regards to implant material and surgical technique. The hooks are the same as secondary predicates, (K033352, K071880, and K031175) in regards to implant materials and surgical technique.

Altus Partners has determined that the modifications to the The Altus Spine Pedicle Screw System does not alter the system function, strength and stability or materials. Therefore, the Altus Spine Pedicle Screw System is substantially equivalent to the predicate devices, and raises no new questions of safety or effectiveness.