January 26, 2021

Altus Partners, LLC
Mark Melton, QA/RA Manager
1340 Enterprise Drive
West Chester, Pennsylvania 19380

Re: K200922
Trade/Device Name: Altus Spine HA Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: December 29, 2020
Received: December 29, 2020

Dear Mark Melton:

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
K200922

Device Name
Altus Spine HA Pedicle Screw System

Indications for Use *(Describe)*

The Altus Spine HA 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 HA Pedicle Screw 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.

The Altus Spine HA Pedicle Screw System may be used for noncervical pedicle fixation via in posterior percutaneous approach with MIS instrumentation for the indications listed above. When used as an anterolateral thoracic/lumbar system the Altus Spine HA Pedicle Screw System may also be used for the same indications listed above as an adjunct to fusion.

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
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CONTACT PERSON: Mark Melton
Regulatory Affairs Specialist
mmelton@altus-spine.com

DATE PREPARED: January 26, 2021
COMMON NAME: Pedicle Screw Spinal System
PROPRIETARY NAME: Altus Spine HA Pedicle Screw System
PRIMARY PREDICATE: Altus Spine Pedicle Screw System (K200322)
ADDITIONAL PREDICATE: Whistler Modular Pedicle Screw System (K182478)

CLASSIFICATION NAME: 21 CFR §888.3070 Thracolumbosacral Pedicle Screw System
PRODUCT CODES: NKB, KWQ
DEVICE CLASS: Class II
MATERIAL: The materials used are Titanium Alloy material that conforms to ASTM F136, Cobalt Chrome that conforms to ASTM F1537 and ASTM F1185 Hydroxyapatite

DEVICE DESCRIPTION:

The Altus Spine HA 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 HA Pedicle Screw System attaches to the vertebral body by means of screws to the non-cervical spine 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, cobalt chrome meeting the requirements of ASTM F1537 and Hydroxyapatite meeting the requirements of ASTM F1185. Other components included in this submission are (e.g., cross connectors, lateral connectors, in-line connectors, dominos, etc.). Only the HA coated screws are supplied sterile packaged. All other components are supplied non-sterile.

INDICATIONS FOR USE:

The Altus Spine HA 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 HA Pedicle Screw 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.

The Altus Spine HA Pedicle Screw System may be used for noncervical pedicle fixation via in posterior percutaneous approach with MIS instrumentation for the indications listed above. When used as an anterolateral thoracic/lumbar system, the Altus Spine HA Pedicle Screw System may also be used for the same indications listed above as an adjunct to fusion.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Altus Spine HA Pedicle Screw System is the same as the primary predicate in regards to indications for use /intended use, technological characteristics, implant materials and surgical technique.

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

No testing is required. (e.g., engineering rational demonstrated that no new worst-case was introduced with the addition of the HA screws and all other components were previously cleared in (K200322). Altus Spine HA Pedicle Screw System are manufactured the same as the primary predicate Altus Spine Pedicle Screw System (K200322). Hydroxyapatite coating and sterile packing are processed the same as the primary predicate Whistler Modular Pedicle Screw System (K182478).

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The Altus Spine HA Pedicle Screw System is substantially equivalent to the predicate devices in terms of intended use, material used, and performance. The Altus Spine HA Pedicle Screw System has a similar design, dimensions and instrumentation to the predicate devices.