



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

April 19, 2023

Re: K230766

Trade/Device Name: Altus Spine Monaco Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: March 20, 2023
Received: March 20, 2023

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,

**Eileen
Cadel -S** Digitally signed
by Eileen Cadel -S
Date: 2023.04.19
15:59:53 -04'00' 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

Indications for Use

510(k) Number (if known)
K230766

Device Name
Altus Spine Monaco Pedicle Screw System

Indications for Use (Describe)

The Altus Spine Monaco 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 Monaco 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 Monaco 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, LLC
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: April 19, 2023

COMMON NAME: Pedicle Screw Spinal System

PROPRIETARY NAME: Altus Spine Monaco Pedicle Screw System

PRIMARY PREDICATE DEVICES: Altus Spine Pedicle Screw System (K211027)

ADDITIONAL PREDICATE DEVICES: Altus Spine Pedicle Screw System (K181339)
Vertebron PSS Pedicle Screw System (K051716)

CLASSIFICATION NAME: 21 CFR §888.3070 Thoracolumbosacral Pedicle Screw System

PRODUCT CODES: NKB

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 Monaco 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 Monaco 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 Monaco 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 Monaco 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 Monaco 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 TECHNOLOGICAL CHARACTERISTICS:

The Altus Spine Monaco Pedicle Screw System is substantially equivalent to the primary predicate in regards to implant materials and surgical technique.

SUMMARY OF NON-CLINICAL TESTS SUBMITTED:

Dynamic Compression Bend, Static Compression Bend, and Static Torsion tests were performed in accordance with ASTM F1717-21. Bench testing demonstrated that the Altus Spine Monaco Pedicle Screw System is substantially equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The Altus Spine Monaco Pedicle Screw System utilizes the same implant materials and surgical technique as the primary predicate device (K211027).

Altus Partners has determined that the modifications to the Altus Spine Monaco Pedicle Screw System do not alter the system function, strength and stability or materials. Therefore, the Altus Spine Monaco Pedicle Screw System is substantially equivalent to the predicate devices.