



Food and Drug Administration
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Altus Partners, LLC
Claudia Hill
Regulatory Affairs Specialist
5129 West Chester Pike
Newtown Square, Pennsylvania 19073

October 16, 2015

Re: K151648

Trade/Device Name: Altus Spine Pedicle Screw System, Altus Spine MIS Pedicle Screw System, Valencia Pedicle Screw System, Valencia MIS Pedicle Screw System

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: Class III

Product Code: NKB, MNI, MNH, KWQ, KWP

Dated: September 26, 2015

Received: September 28, 2015

Dear Ms. Hill:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151648

Device Name

Altus Spine Pedicle Screw System, Altus Spine MIS Pedicle Screw System, Valencia Pedicle Screw System, Valencia MIS 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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8. 510(k) Summary

SUBMITTER: Altus Partners , LLC
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CONTACT PERSON: Claudia Hill
Regulatory Affairs Specialist
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DATE PREPARED: October 12, 2015

COMMON NAME: Pedicle Screw Spinal System

PROPRIETARY NAME: Altus Spine Pedicle Screw System
Altus Spine MIS Pedicle Screw System
Valencia Pedicle Screw System
Valencia MIS Pedicle Screw System

PREDICATE DEVICES: The primary predicate device is the Viper 2 system from DePuy Spine (K131802). The additional predicate devices are Tiger Spine System by CoreLink (K131250), the Altus Spine Pedicle Screw System (K132280).

CLASSIFICATION NAME: 21 CFR §888.3070 Pedicle Screw Spinal System
21 CFR §888.3050 Pedicle Interlaminar Fixation Orthosis
21 CFR §888.3060 Spinal Intervertebral Fixation Orthosis

PRODUCT CODES: NKB, MNI, MNH, KWQ, KWP

DEVICE CLASS: Class III

MATERIAL: The material used is Titanium Alloy material that conforms to ASTM F136.

DEVICE DESCRIPTION:

The Altus Spine Pedicle Screw System is a multiple component, posterior fusion spinal fixation system which consists of pedicle screws, cannulated pedicle screw, reduction screws, extended tab implants, cross-connectors, locking caps, hooks, and rods. 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. 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.

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SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The revised Altus Spine Pedicle Screw System is the same as the predicate (K132280) in regards to implant materials and surgical technique. The Indications for Use have been revised to be consistent with the predicate, Viper 2 (K131802). Components have been added that are substantially equivalent to predicate devices, Viper 2 system (K131802), Tiger Spine System (K131250), Vertebreon PSS Pedicle Screw System (K071376, K033352).

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

There are no new worst case components to this system; therefore no new mechanical testing is warranted.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The revised Altus Spine Pedicle Screw System is the same as the predicate (K132280) in regards to implant materials and surgical technique. The Indications for Use have been revised to be consistent with the predicate, Viper 2 (K131802). Components have been added that are substantially equivalent to predicate devices, Viper 2 system (K131802), Tiger Spine System (K131250), Vertebreon PSS Pedicle Screw System (K071376, K033352).

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