DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 6, 2017

Altus Partners, LLC
Claudia Hill
RA/QA Lead
1340 Enterprise Drive
West Chester, Pennsylvania 19380

Re: K163061
Trade/Device Name: Altus Spine Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 10, 2017
Received: January 11, 2017

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163061

Device Name
Altus Spine Cervical Plate System

Indications for Use *(Describe)*
The Altus Spine Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudosarthrosis and/or failed previous fusions. The Altus Spine Cervical Plate System can be implanted in the sub-axial cervical spine from the C3 through C7 levels.

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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West Chester, PA 19380
Phone: 610-355-4156
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CONTACT PERSON: Claudia Hill, MSME, RAC
Regulatory Affairs & Quality Assurance
chill@altus-spine.com

DATE PREPARED: October 3, 2016

COMMON NAME: Anterior Cervical Plate System

PROPRIETARY NAME: Altus Spine Cervical Plate System

PRIMARY PREDICATE DEVICE: Cardo Medical Cervical Plate System from Cardo Medical Corporation (K091396)

ADDITIONAL PREDICATE DEVICES: Accin Cervical Plate System by Accelerated Innovations, LLC (K073530); Vertebron SCP Cervical Plate System (K040003)

CLASSIFICATION NAME: 21 CFR §888.3060

PRODUCT CODES: KWQ

DEVICE CLASS: Class II

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

DEVICE DESCRIPTION:

The Altus Spine Cervical Plate System is intended for anterior fixation of the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with both self-tapping and self-drilling bone screws. The plates are available in a variety of lengths addressing multiple levels of fixation (one to four). The Altus Spine Cervical Plate System includes graft windows on the longitudinal center line for intraoperative visualization and for screw fixation of bone graft. Fixed or variable bone screws are available in two diameters and a variety of lengths, with the options of either self-tapping or self-drilling threads.

INDICATIONS FOR USE:

The Altus Spine Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudosarthrosis and/or failed previous fusions. The Altus Spine Cervical Plate System can be implanted in the sub-axial cervical spine from the C3 through C7 levels.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of the Altus Spine Cervical plate system is equivalent to the predicate device, except for the locking mechanism. The locking mechanism is provided to ensure that the bone screws remain in place.

SUMMARY OF NON-CLINICAL TESTS SUBMITTED:

Static and dynamic compression bending and static torsion testing in accordance with ASTM F1717 was performed and demonstrated that the Altus Spine Cervical Plate System is substantially equivalent to the predicate devices.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

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