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

January 25, 2017

Altus Partners, LLC
Claudia Hill
Regulatory Affairs Specialist
5149 West Chester Pike
Newtown Square, Pennsylvania 19073

Re: K160976
Trade/Device Name: Altus Spine Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 22, 2016
Received: December 27, 2016

Dear Claudia 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

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)*
K160976

Device Name
Altus Spine Interbody Fusion System

Indications for Use *(Describe)*
The Altus Spine Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Altus Spine Interbody Fusion System is to be combined with cleared supplemental fixation systems, such as the Altus Spine Pedicle Screw System.

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: Claudia Hill, MSME, RAC
Regulatory Affairs & Quality Assurance
chill@altus-spine.com

DATE PREPARED: January 23, 2017

COMMON NAME: Interbody Fusion Device

PROPRIETARY NAME: Altus Spine Interbody Fusion System

PRIMARY PREDICATE DEVICE: Vertebron Interbody Fusion System (K073502)

ADDITIONAL PREDICATE DEVICES: Camber Spine Technologies TLS 5.0 Interbody Cage (K121254); LnK Lumbar Interbody Fusion Cage System (K151140); Interbody Innovation Zeus Intervertebral Fusion Devices (K081614); OsteoMed Spine PrimaLIF LLIF Unitary PEEK Lateral Lumbar Interbody Fusion System (K123207); Choice Spine Lumbar Spacer System (Sabre, Shark, Hornet, Harpoon) (K153107); SpineFrontier Lumbar IBF System (K111553)

CLASSIFICATION NAME: 21 CFR §888.3080 Intervertebral Body Fusion Device

PRODUCT CODES: MAX

DEVICE CLASS: Class II

MATERIAL: The material used is PEEK conforming to ASTM F2026, and titanium alloy conforming to ASTM F136 or tantalum conforming to ASTM F560.

DEVICE DESCRIPTION:

The Altus Spine Interbody Fusion System implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

The Altus Spine Interbody Fusion System implants are made of Polyetheretherketone (PEEK) that conforms to ASTM F2026. This material is utilized due to its radiolucent properties, which aid the surgeon in determining if fusion in the operative site has occurred. Tantalum wire markers are inserted into the components to give surgeons a visual aid in determining the location of the implant, both inter and poster-operatively.

The Altus Spine Interbody Fusion System has a hollow chamber to permit packing with autogenous bone graft to facilitate fusion. The superior and inferior surfaces of the construct have a pattern of teeth to provide increased stability and to help prevent movement of the device.

INDICATIONS FOR USE:

The Altus Spine Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Altus Spine Interbody Fusion System is to be combined with cleared supplemental fixation systems, such as the Altus Spine Pedicle Screw System.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Altus Spine Interbody Fusion System and the predicate (K073502) share the same indications for use, the same material and similar designs. All of the heights, lengths and widths are within range covered by its predicate devices.

SUMMARY OF NON-CLINICAL TESTS SUBMITTED:

Mechanical testing was performed as follows:

- Static Compression Shear and Compression, Dynamic Compression Shear and Compression per ASTM F2077-14 – Test Methods for Intervertebral Body Fusion Devices
- Subsidence per ASTM F2267 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- Expulsion per FDA Guidance

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The revised Altus Spine Interbody Fusion System is the same as the predicate (K073502) in regards to implant materials and surgical technique. The Indications for Use have remained the same. Components have been added that are substantially equivalent to predicate devices.

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