April 19, 2022

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

Re: K211837
Trade/Device Name: Altus Spine Interbody Standalone Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 24, 2022
Received: March 24, 2022

Dear Mr. 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,

for
Brent Showalter, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K211837

Device Name
Altus Spine Interbody Standalone Fusion System

Indications for Use *(Describe)*

The Altus Spine Interbody Standalone Fusion System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

When used with both the cover plate and four (4) provided screws, the Altus Spine Interbody Standalone Fusion System requires no additional supplemental fixation.
In any other instance, additional supplemental fixation systems cleared by the FDA for use in the lumbar spine must be used.

Implants with hyperlordotic angles > 20 degrees, regardless of screw usage, must also be used with additional supplemental fixation (e.g. posterior pedicle screw and rod systems).

The interior of the interbody spacer component is intended to be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

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.

K211837
510(k) Summary

SUBMITTER: Altus Partners
1340 Enterprise Drive
West Chester, PA 19380
Phone: 610-355-4156
Fax: 610-300-3049

CONTACT PERSON: Rand Baker
QA/RA
rbaker@altus-spine.com

DATE PREPARED: April 7, 2022

COMMON NAME: Interbody Fusion Device

PROPRIETARY NAME: Altus Spine Interbody Standalone Fusion System

PRIMARY PREDICATE DEVICES: SeaSpine® Vu a˙POD™ Prime NanoMetalele® Interbody Fusion Device K162351

ADDITIONAL PREDICATE DEVICES: Altus Spine Interbody Fusion System (K182406)

CLASSIFICATION NAME: 21 CFR §888.3080 Intervertebral Body Fusion Device

PRODUCT CODES: OVD

DEVICE CLASS: Class II

MATERIAL: PEEK that conforms to ASTM F2026, Tantalum that conforms to ASTM F560 and Titanium Alloy that conforms to ASTM F136.

DEVICE DESCRIPTION:

The Altus Spine Interbody Standalone 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 device is used singly or in pairs to better approximate the anatomical variations observed in different vertebral levels and/or patient anatomy.

The Altus Spine Interbody Standalone Fusion System implants are made of Polyetheretherketone (PEEK) with Tantalum that conforms to ASTM 2026 and ASTM 560 and Titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

The Altus Spine Interbody Standalone Fusion System has a hollow chamber to permit packing with autogenous bone graft to facilitate fusion, but is the sufficient strength to provide column support even in the absence of fusion for prolonged periods. 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. The anterior superior and inferior surface of the interbody has holes to accept screw to penetrate the intervertebral body endplates for added stability.

INDICATIONS FOR USE:

The Altus Spine Interbody Standalone Fusion System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

When used with both the cover plate and four (4) provided screws, the Altus Spine Interbody Standalone Fusion System requires no additional supplemental fixation.
In any other instance, additional supplemental fixation systems cleared by the FDA for use in the lumbar spine must be used.

Implants with hyperlordotic angles > 20 degrees, regardless of screw usage, must also be used with additional supplemental fixation (e.g. posterior pedicle screw and rod systems).

The interior of the interbody spacer component is intended to be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Altus Spine Interbody Standalone Fusion System is the same as the primary predicate (K162351) in regard to implant material, intended use, surgical technique, target population, biocompatibility, chemical safety, and sterilization. Both systems utilize screws for intrinsic fixation with a backout plate; however, the Altus Spine Interbody Standalone Fusion System requires 4 screws and the SeaSpine® Vu a·POD™ utilizes 2 or 3 screws. Both systems require additional supplemental fixation for implants with hyperlordotic angles > 20 degrees, regardless of screw usage (e.g. posterior pedicle screw and rod systems).

The geometry of the Altus Spine Interbody Standalone Fusion system is similar to the SeaSpine® Vu a·POD™, but not identical with a smaller range of sizes (11-20mm vs. 8-30mm) and a marginally larger footprint (32x24mm, 38x27mm, 42x30mm vs. 31x24mm, 35x27mm); however, the size, footprint, lordotic angles, as well as graft volume and graft area are substantially equivalent to the 2nd predicate (Altus Spine Interbody Fusion System K182406).

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

Testing in accordance with ASTM F2077-14, ASTM 2267-04, and ASTM Draft Std. F04.25.20.02 demonstrates that the Altus Spine Interbody Standalone Fusion System is substantially equivalent to previously FDA cleared integrated ALIFs with standalone indications.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The Altus Spine Interbody Standalone Fusion System is the same as the predicate (K162351) in regard to implant materials and surgical technique. The Indications for Use have remained the same. Components are substantially equivalent to predicate devices, SeaSpine® Vu a˙POD™ Prime NanoMetalene® (K162351) and Altus Spine Interbody Fusion System (K182406).

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