August 20, 2021

Altus Partners, LLC
Mark Melton
QA/RA Manager
1340 Enterprise Drive
West Chester, Pennsylvania 19380

Re: K210887
Trade/Device Name: Altus Spine Sochi OCT Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: May 24, 2021
Received: May 24, 2021

Dear Mark Melton:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: March 16, 2018
See PRA Statement below.

510(k) Number
K210887

Device Name
Altus Spine Sochi OCT Spinal System

Indications for Use *(Describe)*

The Altus Spine Sochi OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3: Traumatic spine fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Tumors involving the cervical spine; Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Altus Spine Sochi OCT System is also intended to restore the integrity of the spinal column even in the absent of fusion for a limited time in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Altus Spine Sochi OCT System may be used with the Theken Coral Spinal System with the use of transition rods and rod connectors.

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
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Phone: 610-356-6148
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CONTACT PERSON: Mark Melton
QA/RA Manager
mmelton@-spine.com

DATE PREPARED: August 20, 2021

COMMON NAME: Altus Spine Posterior Cervical Spinal System

PROPRIETARY NAME: Altus Spine Sochi OCT Spinal System

PREDICATE DEVICES: The Primary predicate device are:
Theken Atoll OCT Spinal System (K083863)

CLASSIFICATION NAME: 21 CFR §888.3075 Posterior Cervical Screw System

PRODUCT CODES: NKG , KWP

DEVICE CLASS: Class II

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

DEVICE DESCRIPTION:

The Altus Spine Sochi OCT Spinal 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 Sochi OCT Spinal System attaches to the vertebral body by means of screws to the 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.

INDICATIONS FOR USE:

The Altus Spine Sochi OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3: Traumatic spine fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Tumors involving the cervical spine; Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

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SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Altus Spine Sochi OCT Spinal System is the same as the primary predicate in regards to implant materials and surgical technique. The only difference between the primary predicate and the Altus Spine Sochi OCT Spinal System is the name. There were no design changes to the primary predicate when compared to the Altus Spine Sochi OCT Spinal System.

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

No testing is required. The Altus Spine Sochi OCT Spinal System are manufactured the same as the primary predicate Theken Atoll OCT Spinal System (K083863).

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The Altus Spine Sochi Spinal System is substantially equivalent to the predicate devices in terms of intended use, material used, and performance. The Altus Spine Sochi OCT Spinal System is the same design, dimensions and instrumentation to the predicate devices.