Alphatec Spine, Inc.
Cynthia Adams
Project Manager, Regulatory Affairs
5818 El Camino Real
Carlsbad, California 92008

August 21, 2018

Re: K181435
Trade/Device Name: ATEC Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: July 30, 2018
Received: August 1, 2018

Dear Ms. Adams:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

for 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181435

Device Name
ATEC Cervical Spacer System

Indications for Use *(Describe)*
The ATEC Cervical Spacer System is intended for spinal fusion procedures at one or two levels from C2 – T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The ATEC Cervical Spacer System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## I. SUBMITTER:

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Phone: (760) 431-9286
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Contact Person: Cynthia Adams
Project Manager, Regulatory Affairs
Contact Phone: (760) 494-6740

Date Summary Prepared: July 30, 2018

## II. DEVICE

Name of Device: ATEC Cervical Spacer System
Common or Usual Name: Intervertebral fusion device with bone graft, Cervical
Classification Name: Intervertebral body fusion device
(21 CFR 888.3080)
Regulatory Class: Class II
Product Code: ODP

## III. LEGALLY MARKETED PREDICATE DEVICES

| 510(k) | Product Code | Trade Name | Manufacturer |
|---|---|---|---|
| **Primary Predicate Device** | | | |
| K171140 | ODP, MQP, MAX | Matrixx™ System | Nexxt Spine |
| **Additional Predicate Devices** | | | |
| K081730 | ODP | Novel® Cervical Spinal Spacer System | Alphatec Spine |
| K180480 | MAX, PHM | ATEC Universal Spacer System | Alphatec Spine |
| K150362 | ODP | CoRoent® Small Interbody System | NuVasive |
| K141376 | ODP, MQP, MAX | Honour™ System | Nexxt Spine |
| K120603 | ODP | Wenzel Spine VariLift Cervical Interbody Fusion Device | Wenzel Spine |
| P980048 | ODP | BAK/Cervical (BAK/C) Interbody Fusion System | Centerpulse Spine-Tech Division |

## IV. DEVICE DESCRIPTION

ATEC Cervical Spacer System includes Battalion Universal Spacer System and ATEC Porous Ti Spacer System that are implanted from an anterior cervical approach.

The ATEC Cervical Spacer System is an intervertebral body fusion system. The implants consist of various lengths, widths, heights and degrees of lordosis to accommodate individual patient anatomy. These implants are manufactured from PEEK (polyetheretherketone) Optima LT1 per ASTM F2026, tantalum per ASTM F560, titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and commercially pure titanium (CPTi Grade 2) per ASTM F67. The device includes rows of teeth on the surface of each end of the device which serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Additionally, the commercially pure titanium implants are offered with a microstructure due to the layering of material that forms the porous geometry. This porous geometry extends to the superior and inferior surfaces of the device for implant fixation. All interbodies feature an internal graft aperture for placement of graft material to promote fusion through the cage.

## V. INDICATIONS FOR USE

The ATEC Cervical Spacer System is intended for spinal fusion procedures at one or two levels from C2 – T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The ATEC Cervical Spacer System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

## VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.

## VII. PERFORMANCE DATA

Nonclinical testing performed on the ATEC Cervical Spacer System supports substantial equivalence to other predicate devices. The following testing was performed:

- Static and dynamic axial compression testing per ASTM F2077
- Static and dynamic torsion testing per ASTM F2077
- Subsidence testing per ASTM F2267
- Expulsion testing
- Particulate and gravimetric analysis per ASTM F1877 and ASTM F1714
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

The results demonstrate that the subject ATEC Cervical Spacer System is substantially equivalent to other predicate devices for nonclinical testing.

**Clinical Information**
Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data. No clinical studies were conducted.

## VIII. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject devices are substantially equivalent to legally marketed devices in regards to indications for use, intended use, design, technology, and performance.