DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 8, 2016

Alphatec Spine, Inc.
Ms. Renée L. Murphy
Senior Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K160958
Trade/Device Name: Battalion Universal Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: PHM, MAX
Dated: August 10, 2016
Received: August 11, 2016

Dear Ms. Murphy:

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 Parts 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" (21CFR 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)*
K160958

Device Name
Battalion Universal Spacer System

Indications for Use *(Describe)*

The Battalion Universal Spacer System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degeneration disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain). The lateral approach is limited to levels T5-6 to T11-T12.

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Battalion Universal Spacer System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with allograft or autograft (e.g. Allogenic bone graft composed of cancellous and/or corticocancellous bone graft) and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4. 510(k) Summary

Device Trade Name	Battalion Universal Spacer System
Manufacturer	Alphatec Spine, Inc. 5818 El Camino Real Carlsbad, CA 92008 USA
Contact	Renée L. Murphy Senior Regulatory Affairs Specialist Phone: (760) 494-6739
Date Prepared	September 1, 2016
Classifications	21 CFR §888.3080, Intervertebral Body Fusion Device
Class	II
Product Code	PHM, MAX
Predicate Device	Battalion Universal Spacer System (K143740) – Primary Predicate Nuvasive CoRoent Thoracolumbar Implants (K150994)

Indications for Use

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The Battalion Universal Spacer System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with allograft or autograft (e.g.,

Allogenic bone graft composed of cancellous and/or corticocancellous bone graft) and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Device Description

The Battalion Universal 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 available in the following two material varieties:

- Polyetheretherketone (PEEK) with tantalum markers
- Commercially pure titanium coated polyetheretherketone (PEEK) with tantalum markers.

All materials are of surgical grade; polyetheretherketone (PEEK Optima LT1) conforms to ASTM F2026, tantalum conforms to ASTM F560, titanium coating conforms to ASTM F1580. All implants are provided sterile.

This system includes inserter instruments used to set the implants between the vertebrae. The patient contacting portions of these instruments are made of surgical grade stainless steel (17Cr-4Ni) per ASTM A564/A564M. These instruments are provided non-sterile and are intended to be cleaned and steam sterilized before each use.

Performance Data (non-clinical)

Mechanical testing performed in accordance with ASTM standards and FDA Spinal Guidance demonstrates acceptable performance characteristics for the modified implant designs. Testing includes Dynamic and Static Axial Compression; Dynamic and Static Axial Torsion, and Dynamic and Static Shear per ASTM F2077 (including Wear Particulate Analysis); Static Expulsion Testing per ASTM F-04.25.02.02; and Static Subsidence Testing per ASTM F2267.

A cadaver study was performed to validate the surgical technique and implantation of this device. Additionally, Bacterial Endotoxin Testing (BET) was conducted in accordance with ANSI/AAMI ST72 and demonstrated endotoxin levels that are within acceptable limits.

Clinical Information

Comprehensive, clinical literature reviews were conducted to assess the safety and efficacy of allograft used in conjunction with this device. This review concluded that there were no additional risks due to the modified indications for this device.

Technological Characteristics

The subject Battalion Universal Spacer System is similar to the predicate devices with respect to indications for use, design, materials, function, and performance.

Conclusion

The information in this 510(k) demonstrates acceptable performance of the Battalion Universal Spacer System and substantial equivalence to the predicate devices.