May 31, 2018

Alphatec Spine, Inc
Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
5818 El Camino Real
Carlsbad, California 92008

Re: K180480
Trade/Device Name: ATEC Universal Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: May 3, 2018
Received: May 4, 2018

Dear Mr. Markovich:

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.

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.

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,

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)*
K180480

Device Name
ATEC Universal Spacer System

Indications for Use *(Describe)*
The ATEC 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 ATEC 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92. The assigned 510(k) number is K180480.

I. SUBMITTER:

Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Phone: (760) 431-9286
Fax: (760) 431-0289

Contact Person: Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
Contact Phone: (760) 494-6893

Date Summary Prepared: February 22, 2018

II. DEVICE

Name of Device: ATEC Universal Spacer System
Common or Usual Name: Interbody fusion device
Classification Name: Intervertebral body fusion device (21 CFR 888.3080)
Regulatory Class: Class II
Product Code: PHM, MAX

III. LEGALLY MARKETED PREDICATE AND REFERENCE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K160958	PHM, MAX	Battalion Universal Spacer System	Alphatec Spine
Additional Predicate Devices			
K080699	MQP, MAX	Novel Spinal Spacer System	Alphatec Spine
K171633	PHM, MAX	NuVasive® TLX Interbody System	NuVasive, Inc.
Reference Devices			
K161485	MAX, ODP	Forticore System	Nanovis, LLC.
K151256	PLF, HRS, HWC	Arthrex BioSync® Bone Wedge	Arthrex, Inc.

IV. DEVICE DESCRIPTION

ATEC Universal Spacer System includes the Battalion Universal Spacer System and Porous Ti Spacer System.

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 come in three material varieties: polyetheretherketone with tantalum markers, commercially pure titanium coated polyetheretherketone with tantalum markers, and titanium alloy (Ti-6Al-4V ELI). 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.

The Porous Ti 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 made of a commercially pure porous titanium (PTi). 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 PTi implant is 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 materials are of surgical grade; polyetheretherketone (PEEK Optima LT1) conforms to ASTM F2026, tantalum conforms to ASTM F560, titanium coating conforms to ASTM F1580, the titanium alloy (Ti-6Al-4V ELI) conforms to ASTM F136, and the commercially pure titanium conforms to ASTM F67. All implants will be provided sterile.

V. INDICATIONS FOR USE

The ATEC 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.

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The ATEC 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.

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

The following non-clinical tests support the substantial equivalence determination as discussed in *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*.

Performance data and engineering analysis demonstrate that the subject ATEC Universal Spacer System is substantially equivalent to the predicates. Testing and analysis include the following:

- Static Compression (per ASTM F2077)
- Dynamic Compression (per ASTM F2077)
- Static Compression Shear (per ASTM F2077)
- Dynamic Compression Shear (per ASTM F2077)
- Gravimetric and Particulate analysis (ASTM F1714 and F1877)
- Push-out (per ASTM F04-25-02-02 Draft)
- Subsidence (per ASTM F2267)
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

Clinical Information

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

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.