



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

July 25, 2018

Re: K181453
Trade/Device Name: ATEC ALIF Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: May 31, 2018
Received: June 1, 2018

Dear Cynthia 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. 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 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

Indications for Use

510(k) Number (if known)

K181453

Device Name

ATEC ALIF Spacer System

Indications for Use (Describe)

The ATEC ALIF 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 ALIF 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 autograft or allograft (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.

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Contact Phone: (760) 494-6740

Date Summary Prepared: May 31, 2018

II. DEVICE

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

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K180480	PHM, MAX	ATEC Universal Spacer System	Alphatec Spine
Additional Predicate Devices			
K160958	PHM, MAX	Battalion Universal Spacer System	Alphatec Spine
K090782	MAX	Novel ALIF Spinal Spacer System	Alphatec Spine
K143740	MAX	Battalion Universal Spacer System	Alphatec Spine
K170962	MAX, PHM	CoRoent Thoracolumbar System	NuVasive, Inc.

IV. DEVICE DESCRIPTION

ATEC ALIF Spacer System includes Battalion Universal Spacer System and Porous Ti Spacer System that are implanted from an anterior or anterolateral approach.

The ATEC ALIF 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, titanium coating per ASTM F1580,

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

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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 mechanical testing performed on predicate devices, as well as engineering analysis, support substantial equivalence of the subject *ATEC ALIF Spacer System*. Therefore, no new mechanical testing was performed for this submission. Bacterial endotoxin testing (BET) was performed 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.