November 6, 2020

Alphatec Spine, Inc.
Sandy Gill
Regulatory Affairs Associate
5818 El Camino Real
Carlsbad, California 92008

Re: K202587
Trade/Device Name: ATEC Lateral Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM, OVD
Dated: September 4, 2020
Received: September 8, 2020

Dear Sandy Gill:

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,

Brent Showalter, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202587

Device Name
ATEC Lateral Interbody System

Indications for Use *(Describe)*
The ATEC Lateral Interbody 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 degenerative 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 Lateral Interbody 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 and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

LIF Anti-Migration Plate (AMP) may be used with ATEC Lateral Interbody spacers to provide integrated fixation. Spacers with >20° lordosis must be used with LIF AMP integrated fixation in addition to supplemental fixation.

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

I. SUBMITTER:

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

Contact Person: Sandy Gill
Regulatory Affairs Associate
Contact Phone: (760) 431-9286

Date Summary Prepared: September 4, 2020

II. DEVICE

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

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K191311	MAX, PHM, OVD	ATEC Lateral Interbody System	Alphatec Spine
Additional Predicate Device			
K160646	MAX, MQP	XYcor Spinal Interbody	Alphatec Spine

IV. DEVICE DESCRIPTION

The ATEC Lateral Interbody System is an intervertebral body fusion system implanted from an anterolateral or lateral approach. The interbody implants consist of various lengths, widths, heights and degrees of lordosis to accommodate individual patient anatomy. These implants are manufactured 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 interbody implants feature an internal graft aperture for placement of graft material to promote fusion through the cage.

The ATEC Lateral Interbody System includes LIF Anti-Migration Plate (AMP) integrated fixation that may be used with all ATEC Lateral Interbody offerings. The LIF AMP integrated fixation includes fixation plates, center locking screws and bone screws manufactured from titanium alloy per ASTM F136.

This 510(k) submission includes sterile packaged AMP plates and screws. The ATEC Lateral Interbody System includes IdentiTi LIF Porous Ti Interbody, Battalion LLIF Spacer System and Transcend LIF Interbody System. Any of the three subsystems may be used with LIF AMP integrated fixation and all implants are offered sterile packaged.

V. INDICATIONS FOR USE

The ATEC Lateral Interbody 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 degenerative 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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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 Lateral Interbody System* supports substantial equivalence to other predicate devices. The following testing was performed:

- Bacterial Endotoxin Test per ANSI/AAMI ST72

The results demonstrate that the subject *ATEC Lateral Interbody 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.

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.