March 1, 2019

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

Re: K183705
Trade/Device Name: IdentiTi™ Porous Ti Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM, OVD, ODP
Dated: December 28, 2018
Received: December 31, 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,

Melissa Hall -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)*
K183705

Device Name
IdentiTi™ Porous Ti Interbody System

Indications for Use *(Describe)*

IdentiTi Cervical Platform

The IdentiTi Porous Ti Interbody 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 IdentiTi Porous Ti Interbody 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.

IdentiTi Thoracolumbar Platform

The IdentiTi Porous Ti 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 IdentiTi Porous Ti 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.

IdentiTi LLIF interbody spacers with >20° lordosis must be used with LLIF AMP integrated fixation in addition to supplemental fixation. IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of 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 section applies only to requirements of the Paperwork Reduction Act of 1995.

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

I. SUBMITTER:

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

Date Summary Prepared: December 28, 2018

II. DEVICE

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

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			
K182746	PHM, MAX, OVD	ATEC ALIF and LLIF Spacer System	Alphatec Spine
K181435	ODP	ATEC Cervical Spacer System	Alphatec Spine

IV. DEVICE DESCRIPTION

The IdentiTi Porous Ti Interbody System is an intervertebral body fusion system implanted from an anterior, anterolateral, lateral or posterior approach. The implants consist of various lengths, widths, heights and degrees of lordosis to accommodate individual patient anatomy. These implants are manufactured from 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 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 IdentiTi Porous Ti Interbody System also includes LLIF AMP integrated fixation to be used with the LLIF interbody offerings. The LLIF AMP integrated fixation includes fixation plates, center locking screws and bone screws manufactured from titanium alloy per ASTM F136.

V. INDICATIONS FOR USE

IdentiTi Cervical Platform

The IdentiTi Porous Ti Interbody 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 IdentiTi Porous Ti Interbody 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.

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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 predicate devices supports the design of the subject IdentiTi Porous Ti Interbody System. Additionally, the following testing was performed on the subject interbody implants:

- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

The results demonstrate that the subject IdentiTi Porous Ti 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.