September 25, 2023

Alphatec Spine, Inc.
Andrew Zhang
Specialist, Regulatory Affairs
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K232097
Trade/Device Name: IdentiTi Interbody Systems
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: July 13, 2023
Received: July 13, 2023

Dear Mr. Zhang:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232097

Device Name
IdentiTi™ ALIF Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi ALIF Standalone lnterbody System is indicated for spinal fusion procedures from L2 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the IdentiTi ALIF Standalone Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels, and for patients with degenerative spondylolisthesis (>Grade 1) and spinal stenosis at one or two adjacent levels, the IdentiTi ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The IdentiTi ALIF Standalone lnterbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate.

When used with three integrated screws, the IdentiTi ALIF Standalone Interbody System implants of ≤20° are a standalone system. When used with fewer than three integrated screws, and for interbody implants of >20°, the IdentiTi ALIF Standalone Interbody System implants must be used with supplemental spinal fixation systems cleared by the FDA for use in the 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232097

Device Name
IdentiTi Porous Ti Interbody System

Indications for Use *(Describe)*
The IdentiTi Porous Ti lnterbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain) at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the IdentiTi Porous Ti Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi Porous Ti lnterbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems, regardless of the use of integrated fixation, 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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K232097
510(k) Summary

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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Phone: (760) 431-6884
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Contact Person: Andrew Zhang
Specialist, Regulatory Affairs
Contact Phone: (760) 494-6806

Date Summary Prepared: August 11, 2023

II. DEVICE

Name of Device: IdentiTi ALIF Interbody Systems:
IdentiTi™ ALIF Standalone Interbody System
IdentiTi™ ALIF Oblique Interbody System
IdentiTi™ ALIF Narrow Interbody System

Common or Usual Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device with Integrated Fixation, Lumbar
Intervertebral Fusion Device, Lumbar
Regulation Number: 21 CFR 888.3080
Regulatory Class: Class II
Product Code: MAX, OVD

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer	Clearance Date
Primary Predicate Device				
K222028	MAX, OVD, PHM	IdentiTi™ Porous Ti Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ PEEK Interbody System, Transcend™ NanoTec™ Interbody System, IdentiTi™ ALIF Standalone Interbody System, IdentiTi™ NanoTec™ ALIF Standalone Interbody System	Alphatec Spine	10/7/2022
Additional Predicate Devices				
K180480	MAX, PHM	ATEC Universal Spacer System	Alphatec Spine	5/31/2018

IV. DEVICE DESCRIPTION

The subject IdentiTi ALIF Interbody Systems are inclusive of IdentiTi ALIF Standalone Interbody System, IdentiTi ALIF Oblique Interbody System, and IdentiTi ALIF Narrow Interbody System. IdentiTi ALIF Oblique and Narrow interbody systems are subsystems of the Alphatec IdentiTi Porous Ti Interbody System.

IdentiTi ALIF Standalone Interbody System is an integrated intervertebral body fusion device with integrated screw fixation for use in anterior and anterolateral procedures. The IdentiTi ALIF Standalone Interbody System consist of interbody devices and bone screw(s) in multiple configurations to accommodate individual patient anatomy. The IdentiTi ALIF Standalone Interbody System interbody spacers are manufactured from a combination of commercially pure porous titanium (CP Ti Grade 2) per ASTM F67 and titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The IdentiTi ALIF Standalone Interbody System interbody spacers are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy. The interbody spacers accept three bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

The IdentiTi ALIF Standalone lnterbody System implants of ≤20° are a standalone system. The IdentiTi ALIF Standalone Interbody System implants of >20° must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine.

The IdentiTi Porous Ti Interbody System is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The IdentiTi interbody spacers are manufactured from commercially pure titanium Grade 2 per ASTM F67 and titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The IdentiTi Porous Ti thoracolumbar platform includes the following sub-systems: IdentiTi ALIF, IdentiTi ALIF Oblique, IdentiTi ALIF Narrow.

The IdentiTi ALIF Standalone Interbody System implants of >20° must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine.

The purpose of this 510(k) submission is to receive clearance for new IdentiTi ALIF Oblique and Narrow interbody implants, modified graft bolts for use with standard IdentiTi ALIF SA interbody implants, and new Class II instruments.

V. INDICATIONS FOR USE

IdentiTi ALIF SA Interbody System

The IdentiTi ALIF Standalone lnterbody System is indicated for spinal fusion procedures from L2 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the

disc confirmed by history and radiographic studies. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the IdentiTi ALIF Standalone Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels, and for patients with degenerative spondylolisthesis (>Grade 1) and spinal stenosis at one or two adjacent levels, the IdentiTi ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The IdentiTi ALIF Standalone lnterbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate.

The IdentiTi ALIF Standalone lnterbody System implants of ≤20° are a standalone system. The IdentiTi ALIF Standalone Interbody System implants of >20° must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine

IdentiTi Porous Ti Interbody System (inclusive of IdentiTi ALIF Oblique and Narrow Interbody Systems):

The IdentiTi Porous Ti lnterbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain) at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the IdentiTi Porous Ti Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi Porous Ti lnterbody System is intended for use on patients who have had at least six months of non- operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems, regardless of the use of integrated fixation, 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

Nonclinical testing performed on the IdentiTi™ ALIF Interbody Systems support substantial equivalence to the predicate devices. The following testing/analysis was performed:

- ASTM F2077 – static & dynamic axial compression, static & dynamic compression-shear
- ASTM F2077 Dynamic Compression-shear Confirmation (30° Spacer),
- ASTM F1714 Gravimetric Analysis (endplate integrity),
- ASTM F1877 Particulate Analysis (endplate integrity),
- ASTM F2267 Static Subsidence,
- Static Push-out (20° Spacer),
- Static Screw Push-out,
- Graft Aperture Area Analysis,
- ASTM F543 Static Torsion,
- ASTM F2193 Static Cantilever Bend

The results demonstrate that the proposed IdentiTi™ ALIF Interbody Systems are substantially equivalent to the 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 the 510(k) submission, it has been determined that the subject devices are substantially equivalent to legally marketed devices in regard to indications for use, intended use, design, technology, and performance.