October 4, 2024

Alphatec Spine, Inc.
Sandy Gill
Manager, Regulatory Affairs
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K242364
Trade/Device Name: IdentiTi™ II Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM, OVD
Dated: August 8, 2024
Received: August 9, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K242364

Device Name
IdentiTi™ II Interbody System

Indications for Use *(Describe)*
The IdentiTi™ II Interbody 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 II System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi II Interbody System is intended for use on patients who have had at least six months of nonoperative 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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without integrated fixation, the system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

AMP™ II Anti-Migration Plate may be used with IdentiTi II LIF interbody spacers to provide integrated fixation. IdentiTi II LIF spacers with >20° lordosis must be used with AMP II Anti-Migration Plate 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 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."

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.
1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 494-6860
Fax: (760) 431-0289

Contact Person: Sandy Gill
Manager, Regulatory Affairs

Date Summary Prepared: October 1, 2024

II. DEVICE

Trade or Proprietary Name:	IdentiTi™ II Interbody System
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral fusion device, lumbar Intervertebral fusion device with integrated fixation, lumbar Intervertebral fusion device with bone graft, thoracic
Regulation Number:	21 CFR 888.3080
Classification:	Class II
Product Code:	MAX, PHM, OVD

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K203714	NuVasive Thoracolumbar Interbody Systems	MAX, MQV, OVD, PHM	December 23, 2021

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K223611	Calibrate™ LTX Interbody System	MAX, PHM, OVD	March 29, 2023
K222028	IdentiTi™ and Transcend™ Interbody Systems	MAX, OVD, PHM	October 07, 2022
K231438	Calibrate™ PSX Interbody System	MAX	July 13, 2023
K222973	IdentiTi™ and Transcend™ Interbody Systems	ODP, OVE	September 27, 2022
K202587	ATEC Lateral Interbody System	MAX, PHM, OVD	November 6, 2020
K182746	ATEC ALIF and LLIF Spacer System	MAX, OVD, PHM	November 27, 2018
K180480	ATEC Universal Spacer System	PHM, MAX	May 31, 2018

Reference Devices:

510(k)	Product Name	Product Code	Clearance Date
K240951	Invictus™ Robotic Navigation Instruments	OLO	June 6, 2024
K192938	Invictus™ Spinal Fixation System	NKB, KWP	December 12, 2019
K161363	Arsenal™ Spinal Fixation System	NKB, KWP, MNH, MNI, OSH	June 10, 2016

IV. DEVICE DESCRIPTION

The *IdentiTi II Interbody System* is a thoracolumbar intervertebral body fusion system designed to be inserted through anterior and posterior surgical approaches. The interbody implants are additively manufactured from titanium powder per ASTM F3001 using a powder bed fusion method. The endplates of the interbody implants contain roughened surface features to mitigate the risk of expulsion. Additionally, the *IdentiTi II* implants are offered with a microporous/macroporous lattice structure that spans the entirety of the implant and extends to the superior and inferior surfaces of the device for biological fixation. The implants consist of various lengths, widths, heights and lordotic options to accommodate individual patient anatomy. All interbody spacers feature an internal graft aperture for placement of graft material to promote fusion through the cage. The internal lattice structure provides additional space for graft packing. The *IdentiTi II LIF* implants may be used with the *AMP II* anti-migration plate and bone screws. The *AMP II* plate and bone screws are manufactured from titanium alloy per ASTM F136.

V. INDICATIONS FOR USE

The IdentiTi™ II Interbody 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 II System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi II Interbody 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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without integrated fixation, the system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

AMP™ II Anti-Migration Plate may be used with IdentiTi II LIF interbody spacers to provide integrated fixation. IdentiTi II LIF spacers with >20° lordosis must be used with AMP II Anti-Migration Plate in addition to supplemental fixation.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject *IdentiTi II Interbody System* are substantially equivalent to the primary predicate *Nuvasive Thoracolumbar Interbody Systems* (K203714), and the additional predicates *IdentiTi and Transcend Interbody Systems* (K222028), *Calibrate LTX Interbody System* (K223611), and *Invictus Spinal Fixation System* (K232275).

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 testing was performed and included, where appropriate for the design, or referenced in predicate 510(k) submissions to support clearance of the *IdentiTi II Interbody System*:

- ASTM F2077 static and dynamic axial compression and compression shear
- ASTM F2267 static subsidence
- ASTM F1714 gravimetric analysis
- ASTM F1877 particle analysis
- Static push-out
- ASTM F1854 stereological analysis
- Static screw push-out
- Bacterial endotoxin testing per ANSI/AAMI ST72

The results demonstrate that the subject *IdentiTi II Interbody System* is substantially equivalent to other predicate devices for nonclinical testing.

VIII. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device is substantially equivalent to legally marketed devices in regard to indications for use, intended use, design, technology, and performance.