September 3, 2025

Alphatec Spine
Alanna Joshi
Senior Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K251575
Trade/Device Name: IdentiTi™ II ALIF Standalone Interbody System; Transcend™ ALIF Standalone Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: August 5, 2025
Received: August 5, 2025

Dear Alanna Joshi:

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,

KATHERINE D. KAVLOCK
-S

for
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251575

Device Name
IdentiTi™ II ALIF Standalone Interbody System; Transcend™ ALIF Standalone Interbody System

Indications for Use *(Describe)*
IdentiTi II ALIF Standalone Interbody System
The IdentiTi II 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. When used with screws or blades, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the IdentiTi II 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 II ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The IdentiTi II ALIF Standalone 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 three (3) screws, interbody implants of ≤20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels without the need for supplemental fixation.

When used with three (3) blades, a combination of three (3) screws and blades, or less than three (3) screws and/or blades, interbody implants must always be used with supplemental fixation.

When used with or without screws and/or blades, interbody implants of >20° must always be used with 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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251575

Device Name
IdentiTi™ II ALIF Standalone Interbody System; Transcend™ ALIF Standalone Interbody System

Indications for Use *(Describe)*
Transend ALIF Standalone Interbody System
The Transcend 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. When used with screws or blades, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the Transcend 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 Transcend ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The Transcend ALIF Standalone 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 three (3) screws, interbody implants of ≤20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels without the need for supplemental fixation.

When used with three (3) blades, a combination of three (3) screws and blades, or less than three (3) screws and/or blades, interbody implants must always be used with supplemental fixation.

When used with or without screws and/or blades, interbody implants of >20° must always be used with 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: Alanna Joshi
Senior Regulatory Affairs Specialist

Date Summary Prepared: May 22, 2025

II. DEVICE

Trade or Proprietary Name:	IdentiTi™ II ALIF Standalone Interbody System; Transcend™ ALIF Standalone Interbody System
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral fusion device, lumbar Intervertebral fusion device with integrated fixation, lumbar
Regulation Number:	21 CFR 888.3080
Classification:	Class II
Product Code:	MAX, OVD

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K241375	IdentiTi™ and Transcend Interbody Systems	OVD, MAX	February 3, 2025

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K160597	INDEPENDENCE® MIS Spacers	OVD, MAX	August 29, 2016
K242364	IdentiTi™ II Interbody System	MAX, PHM, OVD	October 4, 2024
K180480	ATEC Universal Spacer System	MAX, PHM	May 31, 2018
K203742	IdentiTi™ ALIF Standalone Interbody System	OVD	April 9, 2021
K182746	ATEC ALIF and LLIF Spacer System	MAX, OVD, PHM	November 27, 2018
K072253	SYNFIX-LR SPACER	OVD	October 12, 2007
K083475	LUCENT MAGNUM	OVD, MQP	February 13, 2009
K102402	Solus Anterior Lumbar Interbody Fusion (ALIF) Spinal Spacer System	OVD	March 30, 2011

Reference Devices:

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

IV. DEVICE DESCRIPTION

The *IdentiTi II and Transcend ALIF Standalone Interbody Systems* are integrated intervertebral body fusion systems with integrated screw and/or blade fixation for use in anterior and anterolateral procedures. The subject IdentiTi II interbody spacers are additively manufactured via full-melt powder bed fusion (laser melting) from titanium alloy powder (Ti-6Al-4V ELI) conforming to ASTM F3001. The subject Transcend interbody spacers are an assembly of additively manufactured titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F3001, PEEK (polyetheretherketone) Optima LT1 per ASTM F2026, and titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136. The IdentiTi II and Transcend ALIF Standalone interbody spacers are offered in various widths, heights, lengths, lordotic, and anti-migration options to accommodate individual patient anatomy and surgeon preference. The IdentiTi II and Transcend interbody implants are not patient matched. All interbody implants feature an internal graft aperture for placement of graft material to promote fusion through the cage. The interbody spacers accept up to three integrated bone screws and/or blades. The screws and blades are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters, and they mitigate the risk of expulsion of the interbody spacers. To mitigate risk of expulsion, the interbody endplates consist of roughed anti-migration surfaces and teeth. Additionally, the additively manufactured portions of the IdentiTi II (full spacer) and Transcend (anterior faceplate) 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 interbody implants are provided terminally sterile via gamma irradiation while the bone screws, blades, and reusable instruments are provided non-sterile to be steam sterilized by the end user.

V. INDICATIONS FOR USE

IdentiTi II ALIF Standalone Interbody System

The IdentiTi II 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. When used with screws or blades, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the IdentiTi II 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 II ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The IdentiTi II ALIF Standalone 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 three (3) screws, interbody implants of ≤20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels without the need for supplemental fixation.

When used with three (3) blades, a combination of three (3) screws and blades, or less than three (3) screws and/or blades, interbody implants must always be used with supplemental fixation.

When used with or without screws and/or blades, interbody implants of >20° must always be used with supplemental fixation.

Transend ALIF Standalone Interbody System

The Transcend 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. When used with screws or blades, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the Transcend 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 Transcend ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The Transcend ALIF Standalone 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 three (3) screws, interbody implants of ≤20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels without the need for supplemental fixation.

When used with three (3) blades, a combination of three (3) screws and blades, or less than three (3) screws and/or blades, interbody implants must always be used with supplemental fixation.

When used with or without screws and/or blades, interbody implants of >20° must always be used with supplemental fixation.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject *IdentiTi II Interbody System* are substantially equivalent to predicate devices: *IdentiTi II Interbody System* (K242364), *IdentiTi and Transcend Interbody Systems* (K241375), and *Independence MIS Spacers* (K160597).

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 and Transcend ALIF Standalone Interbody Systems*:

- Static and dynamic compression per ASTM F2077
- Static and dynamic compression shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion per ASTM Draft F-04.25.02.02
- Static cantilever bending per ASTM F2193
- Static fixation push-out
- Gravimetric analysis per ASTM F1714
- Particulate analysis per ASTM F1877
- Cadaveric implantation
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72

The results demonstrate that the subject *IdentiTi II and Transcend ALIF Standalone Interbody Systems* are 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.