November 17, 2022

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

Re: K222973
Trade/Device Name: IdentiTi™ and Transcend™ Interbody Systems: IndentiTi™ Cervical Porous Ti Interbody System, IdentiTi™ NanoTec™ Cervical Interbody System, Transcend™ Cervical PEEK Interbody System, Transcend™ NanoTec™ Cervical Interbody System, IdentiTi™ Cervical Standalone Interbody System, IdentiTi™ NanoTec™ Cervical Standalone Interbody Sytem
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: September 27, 2022
Received: September 28, 2022

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)*
K222973

Device Name
IdentiTi Cervical Porous Ti Interbody System

Indications for Use *(Describe)*
The IdentiTi Cervical Porous Ti Interbody System is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K222973

Device Name
IdentiTi™ NanoTec™ Cervical Interbody System

Indications for Use *(Describe)*
The IdentiTi Cervical Interbody System with advanced NanoTec surface treatment is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi NanoTec Cervical Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K222973

Device Name
Transcend Cervical PEEK Interbody System

Indications for Use *(Describe)*
The Transcend Cervical PEEK Interbody System is an anterior cervical interbody fusion system intended for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The Transcend Cervical PEEK Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222973

Device Name
Transcend NanoTec Cervical Interbody System

Indications for Use *(Describe)*
The Transcend Cervical PEEK Interbody System with advanced NanoTec surface treatment is an anterior cervical interbody fusion system intended for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The Transcend NanoTec Cervical Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K222973

Device Name
IdentiTi Cervical Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use in skeletally mature patients for the treatment of cervical degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Standalone Interbody System is intended to be used with autograft, allograft comprised of cortical, cancellous, and/or cortico-cancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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)

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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)*
K222973

Device Name
IdentiTi NanoTec Cervical Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi Cervical Standalone Interbody System with advanced NanoTec surface treatment is a stand-alone anterior cervical interbody fusion system intended for use in skeletally mature patients for the treatment of cervical degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi NanoTec Cervical Standalone Interbody System is intended to be used with autograft, allograft comprised of cortical, cancellous, and/or cortico-cancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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)

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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:

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 431-9286
Fax: (760) 431-0289

Contact Person: Andrew Zhang
Regulatory Affairs Associate
Contact Phone: (760) 494-6806

Date Summary Prepared: September 27, 2022

II. DEVICE

Name of Device:
IdentiTi™ and Transcend™ Interbody Systems:
IdentiTi™ Cervical Porous Ti Interbody System
IdentiTi™ NanoTec™ Cervical Interbody System
Transcend™ Cervical PEEK Interbody System
Transcend™ NanoTec™ Cervical Interbody System
IdentiTi™ Cervical Standalone Interbody System
IdentiTi™ NanoTec™ Cervical Standalone Interbody System

Common or Usual Name: Intervertebral body fusion device
Classification Name: Intervertebral fusion device with bone graft, Cervical
Intervertebral fusion device with integrated fixation, Cervical

Regulatory Class: Class II
Product Code: ODP, OVE

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K172676	ODP	NuVasive® Modulus-C Interbody System	NuVasive
Additional Predicate Devices			
K192582	OVE	NuVasive® CoRoent® Small Interlock™ System	NuVasive

510(k)	Product Code	Trade Name	Manufacturer
K211258	MAX, ODP, OVD, OVE	Endoskeleton TC Interbody System, Endoskeleton TCS Interbody System, Endoskeleton TA Interbody System, Endoskeleton TAS & TAS Hyp Interbody System, Endoskeleton TL Interbody System, Endoskeleton TL Hyp. Interbody System, Endoskeleton TO Interbody System, Endoskeleton TT Interbody System	Medtronic
K211805	MAX, ODP, OVD, PHM	IdentiTi™ Porous Ti Interbody System, Transcend™ PEEK Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ NanoTec™ Interbody System	Alphatec Spine
K220782	MAX, OVD, PHM, OVE	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

IV. DEVICE DESCRIPTION

The IdentiTi and Transcend Interbody Systems are cervical intervertebral body fusion systems designed to be inserted through anterior surgical approaches. The interbody spacers are manufactured from PEEK (polyetheretherketone) Optima LT1 per ASTM F2026, tantalum per ASTM F560, titanium alloy (Ti-6Al-4V ELI), and commercially pure titanium (CPTi Grade 2) per ASTM F67. The interbody spacers are available in the following material options: (1) PEEK (polyetheretherketone) with tantalum and titanium alloy markers, or (2) commercially pure porous titanium (PTi), or (3) a combination of commercially pure porous titanium (CPTi Grade 2) per ASTM F67 and titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

The subject IdentiTi and Transcend Interbody Systems implants consist of various lengths, widths, heights and lordotic options to accommodate individual patient anatomy. To mitigate risk of expulsion, the interbody endplates feature teeth. All interbody spacers feature an internal graft aperture for placement of graft material to promote fusion through the cage. Additionally, the IdentiTi implants are offered with a microstructure due to the layering of material that forms the porous architecture. This porous geometry extends to the superior and inferior surfaces of the device for implant fixation.

The IdentiTi and Transcend NanoTec Interbody Systems implant surfaces have been treated with a 20-40 nanometer thin hydroxyapatite (HA) surface treatment. The surface treatment presents nano-scale topography on the entirety of the implant surface, in addition to macro-/micro-scale topography existing from prior to treatment.

The purpose of this Traditional 510(k) is to receive clearance for expanded indications for cervical spinal instability and use at multiple contiguous levels, and use of allograft consisting of cortical bone, as well as demineralized allograft with bone marrow aspirate.

V. INDICATIONS FOR USE

IdentiTi Cervical Porous Ti Interbody System

The IdentiTi Cervical Porous Ti Interbody System is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

IdentiTi NanoTec Cervical Interbody System

The IdentiTi Cervical Interbody System with advanced NanoTec surface treatment is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi NanoTec Cervical Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

Transcend Cervical PEEK Interbody System

The Transcend PEEK Cervical lnterbody System is an anterior cervical interbody fusion system intended for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The Transcend PEEK Cervical Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

Transcend NanoTec Cervical Interbody System

The Transcend Cervical PEEK Interbody System with advanced NanoTec surface treatment is an anterior cervical interbody fusion system intended for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The Transcend NanoTec Cervical Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

IdentiTi Cervical Standalone Interbody System

The IdentiTi Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use in skeletally mature patients for the treatment of cervical degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Standalone Interbody System is intended to be used with autograft, allograft comprised of cortical, cancellous, and/or cortico-cancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

IdentiTi NanoTec Cervical Standalone Interbody System

The IdentiTi Cervical Standalone Interbody System with advanced NanoTec surface treatment is a stand-alone anterior cervical interbody fusion system intended for use in skeletally mature patients for the treatment of cervical degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi NanoTec Cervical Standalone Interbody System is intended to be used with autograft, allograft comprised of cortical, cancellous, and/or cortico-cancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject IdentiTi and Transcend Interbody Systems are substantially equivalent to the primary predicate NuVasive® Modulus-C Interbody System (K172676), and additional predicates: NuVasive® CoRoent® Small Interlock™ System (K192582), Endoskeleton™ Interbody System (K211258), IdentiTi™ and Transcend™ Interbody Systems (K211805), IdentiTi™ and Transcend™ Interbody Systems (K220782).

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 IdentiTi™ and Transcend™ Interbody Systems.

- ASTM F2077 static and dynamic axial compression and torsion
- ASTM F2267 static subsidence
- Static push-out
- F1714 gravimetric analysis
- F1877 particulate analysis
- Screw push-out

Since the technological characteristics of the subject IdentiTi and Transcend systems are substantially equivalent to the predicate systems, no further clinical or non-clinical testing is required to support the expanded indications for use of the subject systems.

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 regard to indications for use, intended use, design, technology, and performance.