



February 22, 2024

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

Re: K233640

Trade/Device Name: Segmental Plating System (SPS);IdentiTi SPS Interbody System;IdentiTi NanoTec SPS Interbody System; Transcend SPS Interbody System;Transcend NanoTec SPS Interbody System

Regulation Number: 21 CFR 888.3060

Regulation Name: Spinal intervertebral body fixation orthosis

Regulatory Class: Class II

Product Code: KWQ, ODP

Dated: November 13, 2023

Received: January 24, 2024

Dear Andrew 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 (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.

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](mailto: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

## Indications for Use

Submission Number (if known)

K233640

Device Name

Segmental Plating System (SPS);  
IdentiTi SPS Interbody System;  
IdentiTi NanoTec SPS Interbody System;  
Transcend SPS Interbody System;  
Transcend NanoTec SPS Interbody System

Indications for Use (Describe)

### Segmental Plating System (SPS)

The Segmental Plating System (SPS) is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

### IdentiTi SPS Interbody System

The IdentiTi SPS 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 SPS 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 SPS Interbody System

The IdentiTi SPS 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 SPS 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 SPS Interbody System

The Transcend SPS 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 SPS 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 SPS Interbody System

The Transcend SPS 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 SPS 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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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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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.  
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Contact Person: Andrew Zhang  
Regulatory Affairs Specialist  
Contact Phone: (760) 494-6860

Date Summary Prepared: January 24, 2024

**II. DEVICE**

Trade or Proprietary Name: Segmental Plating System (SPS)  
IdentiTi™ SPS Interbody System  
IdentiTi™ NanoTec™ SPS Interbody System  
Transcend™ SPS Interbody System  
Transcend™ NanoTec™ SPS Interbody System

Common Name: Spinal Intervertebral Body Fixation Orthosis  
Intervertebral body fusion device

Classification Name: Appliance, Fixation, Spinal Intervertebral Body  
Intervertebral fusion device with bone graft, Cervical

Regulation Number: 21 CFR 888.3060  
21 CFR 888.3080

Classification: Class II  
Product Code: KWQ, ODP

**III. LEGALLY MARKETED PREDICATE DEVICES**

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K213443	Insignia Anterior Cervical Plate System	KWQ	December 15, 2021

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K211903	Shoreline Threaded TruProfile Plate	KWQ	August 30, 2021
K072703	Pioneer SlimFuse Anterior Cervical Plate System	KWQ	January 10, 2008
K222973	IdentiTi and Transcend Interbody Systems	ODP, OVE	November 17, 2022



## Reference Devices:

510(k)	Product Name	Product Code	Clearance Date
K211805	IdentiTi™ Porous Ti Interbody System, Transcend™ PEEK Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ NanoTec™ Interbody System	MAX, OVD, ODP, PHM	August 26, 2021
K192938	Invictus™ Spinal Fixation System	NKB, KWP	December 12, 2019
K222028	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	MAX, OVD, PHM	October 07, 2022
K140417	Divergence Mini-Plate Anterior Cervical Fusion System	KWQ, ODP	July 09, 2014

**IV. DEVICE DESCRIPTION**

The Segmental Plating System (SPS) is intended for anterior fixation to the cervical spine. The Segmental Plating System (SPS) consists of a variety of sizes of 2 - 4 holes plates and 3.5 mm and 4.0 mm screws that are manufactured from titanium alloy conforming to ASTM F136 and are offered non-sterile. The plate includes a screw anti-backout mechanism. The system will offer instrumentation for the delivery of the plate and screw construct. The instruments in this system are intended for use in surgical procedures. The plate system implants are provided non-sterile to be steam sterilized by the end user.

The IdentiTi and Transcend SPS 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, commercially pure titanium (CP Ti Grade 2) per ASTM F67, and an optional hydroxyapatite nano (HA<sup>nano</sup>) surface treatment. The subject system 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 subject IdentiTi and Transcend NanoTec SPS Interbody Systems interbody implant surfaces have been treated with a 20-40 nanometer thin hydroxyapatite (HA) surface treatment. The surface treatment presents a nano-scale topography on the entirety of the implant surface, in addition to macro-/micro-scale topography existing from prior to HA<sup>nano</sup> treatment. The interbody spacers are provided individually packaged and sterile.

**V. INDICATIONS FOR USE**



### **Segmental Plating System (SPS)**

The Segmental Plating System (SPS) is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

### **IdentiTi SPS Interbody System**

The IdentiTi SPS 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 SPS 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 SPS Interbody System**

The IdentiTi SPS 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 SPS 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 SPS Interbody System**

The Transcend SPS 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 SPS 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 SPS Interbody System**



The Transcend SPS 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 SPS 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.

## VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The subject Segmental Plating System (SPS) is made with similar design, materials, and technological characteristics as those cleared in primary predicate Insignia Anterior Cervical Plate System (K213443) and additional predicates: Shoreline Threaded TruProfile Plate (K211903), and Pioneer SlimFuse Anterior Cervical Plate System (K072703).

The subject IdentiTi and Transcend SPS and IdentiTi and Transcend NanoTec SPS Interbody Systems' implants are a line extension to predicate IdentiTi and Transcend Interbody Systems (K222973). The subject interbody implants are similar in design and made of identical materials as the predicate IdentiTi and Transcend Cervical Interbody System (K222973) except the subject implants have scallop cuts on the anterior wall of the endplates.

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 Segmental Plating and Interbody Systems:

### ASTM F2077:2018 Test Methods for Intervertebral Body Fusion Devices

- Static Compression
- Dynamic Compression
- Static Torsion
- Dynamic Torsion

### ASTM F2267:2004/(R)2018 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

- Subsidence



ASTM Draft Standard F 04.25.02.02 Static Push-out Test Method for Intervertebral Body Fusion Device

- Expulsion

ASTM F1717:2021 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

- Static Compression
- Dynamic Compression
- Static Torsion

The results demonstrate that the subject *Segmental Plating and 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.