February 3, 2025

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

Re: K241375
Trade/Device Name: IdentiTi Porous Ti Interbody System; IdentiTi NanoTec Interbody System; IdentiTi Cervical Porous Ti Interbody System; IdentiTi NanoTec Cervical Interbody System; IdentiTi Cervical Standalone Interbody System; IdentiTi NanoTec Cervical Standalone Interbody System; IdentiTi ALIF Standalone Interbody System; IdentiTi NanoTec ALIF Standalone Interbody System; Transcend PEEK Interbody System; Transcend NanoTec Interbody System; Transcend Cervical PEEK Interbody System; Transcend NanoTec Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM, ODP, OVE
Dated: January 3, 2025
Received: January 3, 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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241375

Device Name

IdentiTi Porous Ti Interbody System
IdentiTi NanoTec Interbody System
IdentiTi Cervical Porous Ti Interbody System
IdentiTi NanoTec Cervical Interbody System
IdentiTi Cervical Standalone Interbody System
IdentiTi NanoTec Cervical Standalone Interbody System
IdentiTi ALIF Standalone Interbody System
IdentiTi NanoTec ALIF Standalone Interbody System
Transcend PEEK Interbody System
Transcend NanoTec Interbody System
Transcend Cervical PEEK Interbody System
Transcend NanoTec Cervical Interbody System

Indications for Use *(Describe)*

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

The IdentiTi Porous Ti 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™ Anti-Migration Plate may be used with IdentiTi LIF interbody spacers to provide integrated fixation. IdentiTi LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.

IdentiTi NanoTec Interbody System
The IdentiTi Interbody System with advanced NanoTec surface treatment 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 NanoTec Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The IdentiTi NanoTec Interbody System is intended for use on patients who have had at 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™ Anti-Migration Plate may be used with IdentiTi NanoTec LIF interbody spacers to provide integrated fixation. IdentiTi NanoTec LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as

cleared by FDA for use in intervertebral body fusion to facilitate fusion.

IdentiTi ALIF Standalone Interbody System
The IdentiTi ALIF Standalone Interbody 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 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.

The IdentiTi ALIF Standalone Interbody 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 ALIF Standalone Interbody 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 NanoTec ALIF Standalone Interbody System
The IdentiTi ALIF Standalone Interbody System with advanced NanoTec surface treatment 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 NanoTec 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 Nanotec ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The IdentiTi NanoTec ALIF Standalone 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.

The IdentiTi NanoTec ALIF Standalone Interbody System implants of ≤20° are a standalone system. The IdentiTi NanoTec 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 in addition to

the integrated screws.

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

The Transcend PEEK 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™ Anti-Migration Plate may be used with Transcend LIF interbody spacers to provide integrated fixation. Transcend LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. Transcend ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.
Transcend NanoTec Interbody System
The Transcend PEEK Interbody System with advanced NanoTec surface treatment 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 Transcend NanoTec Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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

Transcend Cervical PEEK Interbody System
The Transcend PEEK Cervical 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 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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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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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) 431-6884
Fax: (760) 431-0289

Contact Person: Alanna Joshi
Senior Regulatory Affairs Specialist

Date Summary Prepared: January 3, 2025

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
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

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

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Devices:

510(k)	Product Name	Product Codes	Clearance Date
K203714	**NuVasive Thoracolumbar Interbody Systems:** NuVasive CoRoent Thoracolumbar System, NuVasive CoRoent XL Interfixated System, Brigade System, Brigade Lateral System, BASE Interfixated Titanium System, Coalesce Thoracolumbar Interbody Fusion System, NuVasive Cohere Thoracolumbar Interbody System, NuVasive Modulus XLIF Interbody System, NuVasive Modulus TLIF Interbody System, NuVasive Modulus ALIF System NuVasive Attrax Putty	MAX, PHM, OVD, MQV	December 23, 2021
K222276	**CONDUIT™ Cages and FIBERGRAFT™ BG Putty**	ODP, MAX, MQV	October 15, 2022
K231735	**NuVasive CoRoent Small Interlock System**	ODP, OVE	July 11, 2023

Additional Predicate Devices:

510(k)	Product Name	Product Codes	Clearance Date
K222028	**IdentiTi and Transcend Interbody Systems:** 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 7, 2022
K222973	**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	ODP, OVE	November 17, 2022
K232097	**IdentiTi ALIF Interbody Systems**	OVD	September 25, 2023
K233640	**Segmental Plating and Interbody Systems:** Segmental Plating System (SPS), IdentiTi™ SPS Interbody System, IdentiTi™ NanoTec™ SPS Interbody System, Transcend™ SPS Interbody System, Transcend™ NanoTec™ SPS Interbody System	KWQ, ODP	January 24, 2024

IV. DEVICE DESCRIPTION

The IdentiTi and Transcend Interbody Systems are cervical intervertebral body fusion systems designed to be inserted through an anterior surgical approach, and thoracolumbar intervertebral body fusion systems designed to be inserted through anterior and posterior 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 use of the IdentiTi and Transcend Interbody Systems with bone void filler cleared by FDA for use in intervertebral body fusion to facilitate fusion, and to add a nanotechnology claim in alignment with FDA's Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology.

V. INDICATIONS FOR USE

IdentiTi Porous Ti Interbody System

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

The IdentiTi Porous Ti 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™ Anti-Migration Plate may be used with IdentiTi LIF interbody spacers to provide integrated fixation. IdentiTi LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.

IdentiTi NanoTec Interbody System
The IdentiTi Interbody System with advanced NanoTec surface treatment 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.

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

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

IdentiTi ALIF Standalone 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 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.

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 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 NanoTec ALIF Standalone Interbody System
The IdentiTi ALIF Standalone Interbody System with advanced NanoTec surface treatment 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 NanoTec 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 Nanotec ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The IdentiTi NanoTec ALIF Standalone 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.

The IdentiTi NanoTec ALIF Standalone Interbody System implants of ≤20° are a standalone system. The IdentiTi NanoTec 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 in addition to the integrated screws.

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

The Transcend PEEK 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™ Anti-Migration Plate may be used with Transcend LIF interbody spacers to provide integrated fixation. Transcend LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. Transcend ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.

Transcend NanoTec Interbody System
The Transcend PEEK Interbody System with advanced NanoTec surface treatment 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 Transcend NanoTec Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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

In consideration of the FDA's Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, in vitro evaluations were performed to assess that cell-material interactions on the engineered NanoTec™ surface treatment presents nano-scale topography on the entirety of the implant surface, in addition to macro-/micro-scale topography existing prior to treatment micro and nano surface ranging in size between 1-100 nanometers, which exhibit specific osteogenic differentiation. The in vitro study results demonstrated the IdentiTi implants with NanoTec™ surface treatment resulted in statistically significantly increased proliferation, alkaline phosphatase activity (an early indicator of osteogenic differentiation), and mineralization (a late marker of osteogenic differentiation) in both human mesenchymal stem cells (hMSCs) and human osteoblasts (hOBs) compared to other surfaces.

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, compression-shear and torsion
- ASTM F2267 static subsidence
- ASTM F1717 static and dynamic compression, static torsion
- F1714 gravimetric analysis
- F1877 particulate analysis
- Screw push-out
- Static push-out
- Graft aperture area analysis
- ASTM F543 static torsion
- ASTM F2193 static cantilever bending

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 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.