October 7, 2022

Alphatec Spine
Neha Mohindroo
Regulatory Affairs Associate
1950 Camino Vide Roble
Carlsbad, California 92008

Re: K222028
Trade/Device Name: 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
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX,OVD, PHM
Dated: July 8, 2022
Received: July 11, 2022

Dear Ms. Mohindroo:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222028

Device Name

IdentiTi™ Porous Ti Interbody System

Indications for Use *(Describe)*

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 and 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.

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.

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)*

Device Name
IdentiTi™ NanoTec™ Interbody System

K222028

Indications for Use *(Describe)*

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 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 and 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.

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
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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

Device Name
IdentiTi™ ALIF Standalone Interbody System

K222028

Indications for Use *(Describe)*

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 in addition to the integrated screws. The IdentiTi 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.

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 in addition to the integrated screws.

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)*

Device Name
IdentiTi™ NanoTec™ ALIF Standalone Interbody System

K222028

Indications for Use *(Describe)*

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.

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.

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)*
K222028

Device Name
Transcend™ PEEK Interbody System

Indications for Use *(Describe)*
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 and 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.

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)*
K222028

Device Name
Transcend™ NanoTec™ Interbody System

Indications for Use *(Describe)*
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 and 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.

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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510(k) Summary
K222028

I. SUBMITTER:

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

Contact Person: Neha Mohindroo
Regulatory Affairs Associate
Contact Phone: (760) 356-6596

Date Summary Prepared: September 16, 2022

II. DEVICE

Name of Device:
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, lumbar
Intervertebral fusion device with integrated fixation, lumbar

Regulatory Class: Class II
Product Code: MAX, OVD, PHM

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K203201	MAX, PHM, OVD	NuVasive Thoracolumbar Interbody Systems	NuVasive
Additional Predicate Devices			
K220782	MAX, OVD, PHM, OVE	IdentiTi™ and Transcend™ Interbody Systems	Alphatec Spine

510(k)	Product Code	Trade Name	Manufacturer
K183705	MAX, PHM, OVD, ODP	IdentiTi™ Porous Ti Interbody System	Alphatec Spine
K180480	MAX, PHM	ATEC Universal Spacer System	Alphatec Spine
K220782	MAX, OVD, PHM, OVE	IdentiTi™ ALIF Standalone Interbody System	Alphatec Spine
K182746	MAX, PHM, OVD	ATEC ALIF and LLIF Spacer System	Alphatec Spine
K211805	MAX, ODP, OVD, PHM	IdentiTi and Transcend Interbody Systems	Alphatec Spine
K214010	MAX, OVD, OLO	Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology	Medtronic
K210497	MAX, ODP, OVD, OVE, MQP	SeaSpine Spacer System NanoMetalene	SeaSpine Orthopedics Corporation

IV. DEVICE DESCRIPTION

The IdentiTi and Transcend Interbody Systems are 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 the treatment of degenerative spondylolisthesis, multilevel degenerative scoliosis, spinal

stenosis, and sagittal deformity, and use of allogeneic bone consisting of cortical bone, as well as allogeneic bone consisting of demineralized allograft bone with bone marrow aspirate.

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 and 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 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 and 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.

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 and 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 and 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.

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 in addition to the integrated screws. The IdentiTi 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.

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 in addition to the integrated screws.

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.

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.

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 CoRoent Thoracolumbar System* (K203201), and additional predicates: *IdentiTi™ and Transcend™ Interbody Systems* (K220782), *IdentiTi Porous Ti Interbody System* (K183705), *ATEC Universal Spacer System* (K180480), *ATEC ALIF and LLIF Spacer System* (K182746), *IdentiTi and Transcend Interbody Systems* (K211805), *Medtronic Anteralign™ Spinal System with Titan nanoLOCK Surface Technology* (K214010), and *SeaSpine Spacer System NanoMetalene* (K210497).

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, compression-shear and torsion
- ASTM F2267 static subsidence
- ASTM Draft F-04.25.02.02 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.