June 9, 2022

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

Re: K220782
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, IdentiTi™ Cervical Standalone Interbody System, IdentiTi™ NanoTec™ Cervical Standalone Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, OVE, PHM
Dated: March 15, 2022
Received: March 17, 2022

Dear Mr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K220782

Device Name
IdentiTi™ Porous Ti Interbody System

Indications for Use *(Describe)*
The IdentiTi Porous Ti Interbody System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.
Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).
Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

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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Indications for Use

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510(k) Number *(if known)*

K220782

Device Name

IdentiTi™ NanoTec™ Interbody System

Indications for Use *(Describe)*

The IdentiTi Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

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) Number *(if known)*

K220782

Device Name

Transcend™ PEEK Interbody System

Indications for Use *(Describe)*

The Transcend PEEK Interbody System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

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) Number *(if known)*
K220782

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 in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.
Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).
Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
The Transcend NanoTec PEEK Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Type of Use *(Select one or both, as applicable)*

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See PRA Statement below.

510(k) Number *(if known)*
K220782

Device Name
IdentiTi™ ALIF Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi ALIF Standalone Interbody System is indicated for spinal fusion procedures in skeletally mature patients. 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.
The IdentiTi ALIF Standalone Interbody System is intended for use at one or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. 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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

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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See PRA Statement below.

510(k) Number *(if known)*
K220782

Device Name
IdentiTi™ NanoTec™ ALIF Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi ALIF Standalone Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures in skeletally mature patients. 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.

The IdentiTi NanoTec ALIF Standalone Interbody System is intended for use at one or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. 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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft

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

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See PRA Statement below.

510(k) Number *(if known)*
K220782

Device Name
IdentiTi™ Cervical Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The IdentiTi Cervical Standalone Interbody System is to be used with autograft and/or allograft composed of cancellous and/or cortico-cancellous bone graft and implanted via an open, anterior approach. The IdentiTi Cervical Standalone Interbody System is intended to be used with the bone screw fixation provided and requires no additional 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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Indications for Use

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

510(k) Number *(if known)*
K220782

Device Name
IdentiTi™ NanoTec™ Cervical Standalone Interbody System

Indications for Use *(Describe)*
The IdentiTi Cervical Standalone Interbody System with advanced NanoTec surface treatment is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The IdentiTi NanoTec Cervical Standalone Interbody System is to be used with autograft and/or allograft composed of cancellous and/or cortico-cancellous bone graft and implanted via an open, anterior approach. The IdentiTi NanoTec Cervical Standalone Interbody System is intended to be used with the bone screw fixation provided and requires no additional 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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K220782
510k Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER:

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

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

Date Summary Prepared: May 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
IdentiTi™ Cervical Standalone Interbody System
IdentiTi™ NanoTec™ Cervical Standalone Interbody System

Common or Usual Name: Intervertebral body fusion device, lumbar
Intervertebral fusion device, thoracic

Classification Name: Intervertebral fusion device with integrated fixation, lumbar
Intervertebral fusion device with integrated fixation, cervical
Class II

Regulatory Class: MAX, OVD, PHM, OVE

Product Code:

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K211805	PHM, MAX, OVD, ODP	IdentiTi™ Porous Ti Interbody System,	Alphatec Spine

510(k)	Product Code	Trade Name	Manufacturer
		Transcend™ PEEK Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ NanoTec™ Interbody System	
Additional Predicate Devices			
K183705	MAX, PHM, OVD, ODP	IdentiTi™ Porous Ti Interbody System	Alphatec Spine
K180480	MAX, PHM	ATEC Universal Spacer System	Alphatec Spine
K202812	OVE	IdentiTi™ Cervical Standalone Interbody System	Alphatec Spine
K203742	OVD	IdentiTi™ ALIF Standalone Interbody System	Alphatec Spine
K202889	HRS, HWC	Valkyrie Thoracic Fixation System	JM Longyear Manufacturing, LLC

IV. DEVICE DESCRIPTION

The IdentiTi and Transcend Interbody Systems are cervical 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 (CP Ti 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 IdentiTi ALIF and Cervical Standalone Interbody Systems accept two or three bone screws/bolts that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

V. INDICATIONS FOR USE

IdentiTi Porous Ti Interbody System

The IdentiTi Porous Ti Interbody System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

IdentiTi NanoTec Interbody System

The IdentiTi Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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 for use with autograft and/or

allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Transcend PEEK Interbody System

The Transcend PEEK Interbody System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Transcend NanoTec Interbody System

The Transcend PEEK Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.

Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Transcend NanoTec PEEK Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

IdentiTi ALIF Standalone Interbody System

The IdentiTi ALIF Standalone Interbody System is indicated for spinal fusion procedures in skeletally mature patients. 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.

The IdentiTi ALIF Standalone Interbody System is intended for use at one or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. 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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

IdentiTi NanoTec ALIF Standalone Interbody System

The IdentiTi NanoTec ALIF Standalone Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures in skeletally mature patients. 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.

The IdentiTi NanoTec ALIF Standalone Interbody System is intended for use at one or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. 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 for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

IdentiTi Cervical Standalone Interbody System

The IdentiTi Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The IdentiTi Cervical Standalone

Interbody System is to be used with autograft and/or allograft composed of cancellous and/or cortico-cancellous bone graft and implanted via an open, anterior approach. The IdentiTi Cervical Standalone Interbody System is intended to be used with the bone screw fixation provided and requires no additional fixation.

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 as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The IdentiTi NanoTec Cervical Standalone Interbody System is to be used with autograft and/or allograft composed of cancellous and/or cortico-cancellous bone graft and implanted via an open, anterior approach. The IdentiTi NanoTec Cervical Standalone Interbody System is intended to be used with the bone screw fixation provided and requires no additional fixation.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The subject IdentiTi and Transcend NanoTec Interbody Systems incorporate a nano-scale hydroxyapatite surface treatment, identical to that provided on devices cleared in IdentiTi™ and Transcend™ Interbody Systems (K211805) and Valkyrie Thoracic Fixation System (K202889). The subject IdentiT and Transcend NanoTec implants are a line extension to primary predicate IdentiTi™ and Transcend™ Interbody Systems (K211805) and additional predicates: IdentiTi™ Porous Ti Interbody System (K183705), ATEC Universal Spacer System (K180480), IdentiTi™ Cervical Standalone Interbody System (K202812), and IdentiTi™ ALIF Standalone Interbody System (K203742). The IdentiTi™ Nanotec™ ALIF Standalone and IdentiTi™ NanoTec™ Cervical Standalone implants contain a titanium alloy structure that is treated with nano-scale hydroxyapatite surface treatment, this material and nano-scale coating is identical to screws cleared in predicate Valkyrie Thoracic Fixation System (K202889). The indications for use are substantially equivalent to predicate devices.

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

Mechanical testing performed on the predicates applies to the modified devices because there is no difference in size, dimension, raw material or manufacturing method or equipment with the exception of a nanometer thin layer of hydroxyapatite applied to the surface.

Nonclinical testing performed on the IdentiTi and Transcend Interbody Systems supports substantial equivalence to other predicate devices. The following testing was performed:

- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

The results demonstrate that the subject IdentiTi and Transcend Interbody Systems are substantially equivalent to other predicate devices for nonclinical testing.

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.