September 22, 2021

Alphatec Spine, Inc.
Ms. Sandy Gill
Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K211805
Trade/Device Name: IdentiTi™ Porous Ti Interbody System, Transcend™ PEEK Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ NanoTec™ Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, ODP, PHM
Dated: August 25, 2021
Received: August 26, 2021

Dear Ms. Gill:

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

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

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

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

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

Sincerely,

Brent L. 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)*
K211805

Device Name
Transcend™ NanoTec™ Interbody System

Indications for Use *(Describe)*

Transcend NanoTec Cervical Platform

The Transcend PEEK Cervical Interbody System with advanced NanoTec surface treatment is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Transcend PEEK Cervical NanoTec Interbody System is intended for use with supplemental fixation systems and with autograft or allograft (e.g., allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients should have had six weeks of non-operative treatment.

Transcend NanoTec Thoracolumbar Platform

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.

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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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)*
K211805

Device Name
IdentiTi™ Porous Ti Interbody System

Indications for Use *(Describe)*

IdentiTi Cervical Platform

The IdentiTi Cervical Porous Ti Interbody System is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

IdentiTi Thoracolumbar Platform

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.

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.

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)*
K211805

Device Name
Transcend™ PEEK Interbody System

Indications for Use *(Describe)*

Transcend Cervical Platform

The Transcend PEEK Cervical Interbody System is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Transcend PEEK Cervical Interbody System is intended for use with supplemental fixation systems and with autograft or allograft (e.g., allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients should have had six weeks of non-operative treatment.

Transcend Thoracolumbar Platform

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.

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.

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)*
K211805

Device Name
IdentiTi™ NanoTec™ Interbody System

Indications for Use *(Describe)*

IdentiTi NanoTec Cervical Platform

The IdentiTi Cervical Interbody System with advanced NanoTec surface treatment is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The IdentiTi Cervical NanoTec Interbody System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

IdentiTi NanoTec Thoracolumbar Platform

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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K211805
510K Summary

I. SUBMITTER:

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 431-9286
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Contact Person: Sandy Gill
Regulatory Affairs Specialist
Contact Phone: (760) 431-9286

Date Summary Prepared: September 13, 2021

II. DEVICE

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

Common or Usual Name: Intervertebral body fusion device

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

Regulatory Class: Class II

Product Code: MAX, ODP, OVD, PHM

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K183705	PHM, MAX, OVD	IdentiTi Porous Ti Interbody System	Alphatec Spine
Additional Predicate Devices			
K202587	MAX, OVD, PHM	ATEC Lateral Interbody System	Alphatec Spine
K201614	MAX, OVD	TxTiHA™ IBF System, AxTiHA™ Stand-Alone ALIF System	Innovasis, Inc.
K181435	ODP	ATEC Cervical Spacer System	Alphatec Spine
K203201	MAX, PHM, OVD	CoRoent Thoracolumbar System	NuVasive, Inc.

IV. DEVICE DESCRIPTION

The *IdentiTi and Transcend Interbody Systems* are cervical and thoracolumbar intervertebral body fusion systems designed to be inserted through anterior and lateral 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).

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 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 and Transcend Interbody Systems* also includes LIF AMP integrated fixation to be used with the LIF interbody offerings. The LIF AMP integrated fixation includes fixation plates, center locking screws and bone screws manufactured from titanium alloy per ASTM F136.

V. INDICATIONS FOR USE

IdentiTi Porous Ti Interbody System

IdentiTi Cervical Platform

The IdentiTi Cervical Porous Ti Interbody System is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

IdentiTi Thoracolumbar Platform

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.

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 NanoTec Interbody System

IdentiTi NanoTec Cervical Platform

The IdentiTi Cervical Interbody System with advanced NanoTec surface treatment is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The IdentiTi Cervical NanoTec Interbody System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

IdentiTi NanoTec Thoracolumbar Platform

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.

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

Transcend Cervical Platform

The Transcend PEEK Cervical Interbody System is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Transcend PEEK Cervical Interbody System is intended for use with supplemental fixation systems and with autograft or allograft (e.g., allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients should have had six weeks of non-operative treatment.

Transcend Thoracolumbar Platform

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.

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 NanoTec Interbody System

Transcend NanoTec Cervical Platform

The Transcend PEEK Cervical Interbody System with advanced NanoTec surface treatment is intended for spinal fusion procedures at one or two levels from C2-T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Transcend PEEK Cervical NanoTec Interbody System is intended for use with supplemental fixation systems and with autograft or allograft (e.g., allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients should have had six weeks of non-operative treatment.

Transcend NanoTec Thoracolumbar Platform

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.

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.

VI. TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES

The subject *IdentiTi and Transcend NanoTec Interbody Systems* incorporate a nano-scale hydroxyapatite surface treatment, identical to that provided on devices cleared in TxTiHA™ IBF System, AxTiHA™ Stand-Alone ALIF System (K201614). The subject IdentiTi and Transcend NanoTec implants are a line extension to primary predicate, IdentiTi Porous Ti Interbody System (K183705) and additional predicate devices: ATEC Lateral Interbody System (K202587) and ATEC Cervical Spacer System (K181435). Additionally, the indications for use have been updated to remove the limitation on the lateral approach. 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.