April 9, 2021

Alphatec Spine Inc.
Cynthia Dorne
Manager, Regulatory Affairs
5818 El Camino Real
Carlsbad, California 92008

Re: K203742
Trade/Device Name: IdentiTi™ ALIF Standalone Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 18, 2021
Received: March 19, 2021

Dear Cynthia Dorne:

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 Showalter -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203742

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:

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Phone: (760) 431-6884
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Contact Person: Cynthia Dorne
Manager, Regulatory Affairs
Contact Phone: (760) 494-6740

Date Summary Prepared: December 20, 2020

II. DEVICE

Name of Device:	IdentiTi™ ALIF Standalone Interbody System
Common or Usual Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification Name:	Intervertebral Body Fusion Device (21 CFR 888.3080)
Regulatory Class:	Class II
Product Code:	OVD

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate			
K182139	OVD	AXTi™ Titanium Stand-Alone ALIF System	Innovasis®
Additional Predicates			
K183705	ODP, PHM, MAX, OVD	IdentiTi™ Porous Ti Interbody System	Alphatec Spine®
K150643	OVD	Centinel Spine STALIF TT, STALIF MIDLINE, MIDLINE II, MIDLINE II-Ti	Centinel Spine®
K083475	MAX	Lucent® Magnum+	Spinal Elements®
K180480	PHM,MAX	ATEC Universal Spacer System	Alphatec Spine®
K182746	MAX,PHM,OVD	ATEC ALIF and LLIF Spacer System	Alphatec Spine®
K011556	KWQ	Aesculap MACS HMA Spinal Stabilization System	Aesculap®

510(k)	Product Code	Trade Name	Manufacturer
K102334	KWQ	Quandary Medical Trans1 AxiaLIF Plus	Trans1®
K073109	OVD	STALIF TT Intervertebral Body Fusion System	Surgicraft®
K181818	OVD, MAX	Spineart Scarlet AL-T	Spineart®
K162236	OVD	Ax Stand-Alone ALIF System	Innovasis®
K202812	OVE	IdentiTi Cervical Standalone Interbody System	Alphatec Spine®
K203056	NKB,KWP	Invictus Spinal Fixation System	Alphatec Spine®
K161363	NKB,OSH,MNI,MNH,KWP	Arsenal Spinal Fixation System	Alphatec Spine®

IV. DEVICE DESCRIPTION

The IdentiTi™ ALIF Standalone (SA) Interbody System is an integrated intervertebral body fusion device implanted from an anterior or anterolateral approach. The IdentiTi ALIF Standalone Interbody System interbody spacers are manufactured from 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 IdentiTi ALIF Standalone Interbody System interbody spacers are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy. All interbody spacers feature an internal graft aperture for placement of graft material to promote fusion through the cage. The interbody spacer includes three screw holes to accept bone screws and bolts that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

V. INDICATIONS FOR USE

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.

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

Nonclinical testing performed on the IdentiTi™ ALIF Standalone Interbody System supports substantial equivalence to the predicate devices. The following testing/analysis was performed:

- ASTM F2077 – static & dynamic axial compression, static & dynamic compression-shear
- ASTM F1877 – particulate analysis
- ASTM F1714 – gravimetric analysis
- ASTM F2267 – subsidence
- Static push-out
- Screw push-out

The results demonstrate that the proposed IdentiTi™ ALIF Standalone Interbody System is substantially equivalent to the 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 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.