December 18, 2020

Alphatec Spine, Inc.
Ruby Zheng
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K202812
Trade/Device Name: IdentiTi™ Cervical Standalone Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: November 25, 2020
Received: November 27, 2020

Dear Ruby Zheng:

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, 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)*

K202812

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 bone graft and/or allogeneic bone graft composed of cancellous and/or cortico-cancellous bone 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)

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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Contact Person: Ruby Zheng
Regulatory Affairs Specialist
Contact Phone: (760) 494-6884

Date Summary Prepared: November 25, 2020

II. DEVICE

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

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate			
K200543	OVE	Nexxt Matrixx Stand Alone Cervical-Turn Lock System	Nexxt Spine
Additional Predicate			
K170953	OVE	TOMCAT Cervical Spinal System	Choice Spine
K183705	ODP, OVD, PHM, MAX	ATEC IdentiTi Porous Ti Interbody System	Alphatec Spine

IV. DEVICE DESCRIPTION

The *IdentiTi™ Cervical (IdentiTi-C) Standalone Interbody System* is an integrated intervertebral body fusion device for use in Anterior Cervical Discectomy and Fusion (ACDF) Procedures. The *IdentiTi Cervical Standalone Interbody System* consists of

integrated interbody spacers and bone screws in multiple configurations to accommodate individual patient anatomy.

The *IdentiTi Cervical 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 Cervical Standalone Interbody System* interbody spacers are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy.

The anterior face of the interbody spacer includes two screw holes to accept two bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters. All interbody spacers feature an internal graft aperture for placement of graft material to promote fusion through the cage.

The subject interbody spacers are provided individually packed and sterile. The subject bone screws are provided non-sterile to be cleaned and steam-sterilized by the end user.

The system provides reusable instruments that support varying surgical techniques, common with the ACDF approach, and are made of stainless steel and other materials. They are provided non-sterile to be cleaned and sterilized by the end user.

V. INDICATIONS FOR USE

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 bone graft and/or allogeneic bone graft composed of cancellous and/or cortico-cancellous bone 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.

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™ Cervical 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, static & dynamic torsion

- ASTM F1877 – particulate analysis
- ASTM F1714 – gravimetric analysis
- ASTM F2267 – subsidence
- ASTM F-04.25.02.02 – push-out
- Static screw push-out

The results demonstrate that the proposed *IdentiTi™ Cervical 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 this 510(k) submission, it has been determined that the subject devices are substantially equivalent to legally marketed devices in regards to indications for use, intended use, design, technology, and performance.