October 6, 2023

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

Re: K232173
Trade/Device Name: Ascend™ VBR System, Ascend™ NanoTec™ VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: July 21, 2023
Received: July 21, 2023

Dear Sandy 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 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)*

K232173

Device Name

Ascend™ VBR System

Indications for Use *(Describe)*

The Ascend VBR System is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Ascend VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Ascend VBR System is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Ascend VBR System is optional.

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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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)*

K232173

Device Name

Ascend™ NanoTec™ VBR System

Indications for Use *(Describe)*

The Ascend NanoTec VBR System with advanced NanoTec surface treatment is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Ascend NanoTec VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Ascend NanoTec VBR System is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Ascend NanoTec VBR System is optional.

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 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: Sandy Gill
Sr. Regulatory Affairs Specialist

Date Summary Prepared: October 5, 2023

II. DEVICE

Trade or Proprietary Name:	Ascend™ VBR Systems: Ascend™ VBR System, Ascend™ NanoTec™ VBR System
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Vertebral Body Replacement Device Spinal Vertebral Body Replacement Device - Cervical
Regulation Number:	21 CFR 888.3060
Classification:	Class II
Product Code:	MQP, PLR

III. LEGALLY MARKETED DEVICES

Primary Predicate Device:

510(k)	Product Name	Clearance Date
K192117	Small VBR™	11/1/2019

Additional Predicate Devices:

510(k)	Product Name	Clearance Date
K050553	Novel Spinal Spacer System	04/18/2005
K193506	NuVasive X-Core® Expandable VBR System, NuVasive X-Core® Mini Cervical Expandable VBR System	02/26/2020

References Devices:

510(k)	Product Name	Clearance Date
K222028	IdentiTi™ and Transcend™ Interbody Systems	10/07/2022
K180480	IdentiTi™ Porous Ti Interbody System	05/31/2018
K211805	IdentiTi™ and Transcend™ Interbody Systems	09/22/2021
K161363	Arsenal Spinal Fixation System	06/10/2016
K192938	Invictus™ Spinal Fixation System	12/12/2019

510(k)	Product Name	Clearance Date
K222973	IdentiTi™ and Transcend™ Interbody Systems	11/17/2022

IV. DEVICE DESCRIPTION

The Ascend VBR Systems are cervical and thoracolumbar vertebral body replacement systems designed to be inserted in the anterior, anterolateral, lateral, and posterior approaches. The implants consist of VBR cores and endplates offered in a range of diameters and heights, endplates, footprints, and lordotic angles to accommodate individual patient anatomy.

The cores are made of titanium alloy per ASTM F136 and the endplates are made of titanium alloy per ASTM F136 or are made of hybrid titanium consisting of commercially pure porous titanium CP-Ti Grade 2 per ASTM F67 and titanium alloy per ASTM F136.

The modular endplates are offered with an optional 20-40 nanometer thin hydroxyapatite 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.

V. INDICATIONS FOR USE

Ascend VBR System

The Ascend VBR System is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Ascend VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Ascend VBR System is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Ascend VBR System is optional.

Ascend NanoTec VBR System

The Ascend NanoTec VBR System with advanced NanoTec surface treatment is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Ascend NanoTec VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Ascend NanoTec VBR System is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Ascend NanoTec VBR System is optional.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject devices 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 performance testing was conducted or adopted for the subject Ascend VBR Systems:

- Static and Dynamic Axial Compression per ASTM F2077
- Static and Dynamic Torsion per ASTM F2077
- Static Subsidence per ASTM F2267
- Static Push-out
- Gravimetric Analysis per ASTM F1714
- Particulate Analysis per ASTM F1877
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2019
- Biocompatibility Testing per ISO 10993-1

Testing results demonstrated the subject Ascend VBR Systems are substantially equivalent when compared to other legally marketed devices cleared by FDA.

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.