July 13, 2023

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

Re: K231438
Trade/Device Name: Calibrate PSX Interbody System, Calibrate NanoTec PSX Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 17, 2023
Received: May 17, 2023

Dear Ms. Bhuptani:

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 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)*
K231438

Device Name
Calibrate PSX Interbody System

Indications for Use *(Describe)*
Calibrate PSX Interbody System
The Calibrate PSX Interbody System is indicated for spinal fusion procedures from L1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the Calibrate PSX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate PSX 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 allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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PRAStaff@fda.hhs.gov

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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)*
K231438

Device Name
Calibrate NanoTec PSX Interbody System

Indications for Use *(Describe)*
Calibrate NanoTec PSX Interbody System
The Calibrate PSX Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from L1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the Calibrate NanoTec PSX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate NanoTec PSX 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 allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the 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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K231438
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: Unnati Bhuptani
Sr. Regulatory Affairs Specialist
Contact Phone: (760) 356-6711

Date Summary Prepared: May 16, 2023

II. DEVICE

Name of Device: Calibrate PSX Interbody System
Calibrate NanoTec PSX Interbody System
Common or Usual Name: Intervertebral body fusion device
Classification Name: Intervertebral fusion device with bone graft, lumbar (21 CFR 888.3080)
Regulatory Class: Class II
Product Code: MAX

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K222028	MAX, OVD, PHM	IdentiTi and Transcend Interbody System	Alphatec Spine
Additional Predicate Devices			
K211873	MAX	PSX Interbody System	Alphatec Spine

IV. DEVICE DESCRIPTION

The subject Calibrate PSX Interbody Systems (inclusive of Calibrate PSX Interbody System and Calibrate NanoTec PSX Interbody System) are lordotic expandable lumbar intervertebral body fusion systems designed to be inserted through a posterior surgical approach. The subject interbody spacers are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The subject Calibrate NanoTec PSX Interbody System interbody implant endplate surfaces have been treated with a 20-40 nanometer thin hydroxyapatite (HA) surface treatment. The Calibrate PSX Interbody Systems consist of a variety of shapes and sizes of interbody spacers, inserters, trials, and general instruments to create lordotic expansion, restore sagittal alignment, and provide indirect decompression.

Implants are offered with anti-migration teeth and grit-blast treatment on the bone-contacting endplate surfaces.

The purpose of this Traditional 510(k) is to receive clearance for new Calibrate PSX Interbody System and Calibrate NanoTec PSX Interbody System implants, and expanded indications for use for Calibrate PSX Interbody System implants, previously cleared in K211873.

V. INDICATIONS FOR USE

Calibrate PSX Interbody System

The Calibrate PSX Interbody System is indicated for spinal fusion procedures from L1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the Calibrate PSX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate PSX 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 allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the lumbar spine.

Calibrate NanoTec PSX Interbody System

The Calibrate PSX Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from L1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the Calibrate NanoTec PSX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate NanoTec PSX 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 allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the lumbar spine.

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 Calibrate PSX Interbody Systems supports substantial equivalence to other predicate devices. The following testing was performed:

- Static and Dynamic Axial Compression (per ASTM F2077)
- Static and Dynamic Compression Shear (per ASTM F2077)
- Push-out
- Subsidence analysis
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

The results demonstrate that the subject Calibrate PSX 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.