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

September 20, 2024

Re: K242147
Trade/Device Name: Calibrate LTX Interbody System; Calibrate NanoTec LTX Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM
Dated: July 22, 2024
Received: July 23, 2024

Dear Unnati 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.09.20 09:07:37 -04'00'

for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242147

Device Name

Calibrate LTX Interbody System
Calibrate NanoTec LTX Interbody System

Indications for Use *(Describe)*

Calibrate LTX Interbody System
The Calibrate LTX Interbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of a symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain) 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 LTX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate LTX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Calibrate LTX spacers expanded greater than 20° have integrated fixation tabs and must be used with LTX bone screws in addition to supplemental fixation. Calibrate LTX spacers without integrated fixation tabs may be used with AMP-LTX System as integrated fixation in addition to supplemental fixation.

Calibrate NanoTec LTX Interbody System
The Calibrate LTX Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of a symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain) 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 LTX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate NanoTec LTX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Calibrate NanoTec LTX spacers expanded greater than 20° have integrated fixation tabs and must

be used with AMP-LTX bone screws in addition to supplemental fixation. Calibrate NanoTec LTX spacers without integrated fixation tabs may be used with AMP-LTX System as integrated fixation 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.

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.

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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:**

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 494-6860
Fax: (760) 431-0289

Contact Person: Unnati Bhuptani
Sr. Regulatory Affairs Specialist

Date Summary Prepared: September 19, 2024

II. DEVICE

Trade or Proprietary Name:	Calibrate LTX Interbody System
Common Name:	Calibrate NanoTec LTX Interbody System Intervertebral body fusion device
Classification Name:	Intervertebral fusion device with bone graft, lumbar Intervertebral fusion device with integrated fixation, lumbar Intervertebral fusion device with bone graft, thoracic
Regulation Number:	21 CFR 888.3080
Classification:	Class II
Product Code:	MAX, OVD, PHM

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K203714	NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty	MAX, OVD, PHM, MQV	December 23, 2021

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K222028	IdentiTi and Transcend Interbody Systems	MAX, OVD, PHM	October 7, 2022
K223611	Calibrate LTX Interbody System	MAX, OVD, PHM	March 29, 2023
K211805	IdentiTi™ Porous Ti Interbody System, Transcend™ PEEK Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ NanoTec™ Interbody System	MAX, OVD, ODP, PHM	August 26, 2021
K202587	ATEC Lateral Interbody System	MAX, OVD, PHM	November 06, 2020

Reference Devices:

510(k)	Product Name	Product Code	Clearance Date
K221926	Invictus™ Spinal Fixation System	PML, NKB, KWP, KWQ	December 20, 2022
K161363	Arsenal Spinal Fixation System	NKB, KWP, MNH, MNI, OSH	June 10, 2016
K192938	Invictus Spinal Fixation System	NKB, KWP	December 12, 2019
K240951	Invictus Robotic Navigation Instruments	OLO	June 06, 2024

IV. DEVICE DESCRIPTION

The subject Calibrate LTX Interbody Systems are lordotic expandable thoracolumbar intervertebral body fusion systems designed to be inserted through a lateral or anterolateral surgical approach. The subject interbody spacers are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The subject Calibrate NanoTec LTX Interbody System interbody implant endplate surfaces have been treated with a 20-40 nanometer thin hydroxyapatite (HA) surface treatment. The Calibrate LTX 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. Certain Calibrate LTX Interbody Systems' offerings also accept fixation bone screws manufactured from titanium alloy per ASTM F136.

The purpose of this Traditional 510(k) is to receive clearance for the new sizes of the modified design of the interbody spacer, including a sterile offering of interbody spacer with hydroxyapatite surface treatment, sterile offering of AMP-LTX anti-migration plate and expanded indications for use for the Calibrate LTX Interbody System, previously cleared in K223611.

V. INDICATIONS FOR USE

Calibrate LTX Interbody System

The Calibrate LTX Interbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of a symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain) 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 LTX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate LTX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

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Calibrate NanoTec LTX Interbody System

The Calibrate LTX Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of a symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain) 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 LTX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate NanoTec LTX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogeneic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Calibrate NanoTec LTX spacers expanded greater than 20° have integrated fixation tabs and must be used with AMP-LTX bone screws in addition to supplemental fixation. Calibrate NanoTec LTX spacers without integrated fixation tabs may be used with AMP-LTX System as integrated fixation in addition to supplemental fixation.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject *Calibrate LTX Interbody Systems* are substantially equivalent to the primary predicate *NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty* (K203714), the additional predicates *IdentiTi™ and Transcend™ Interbody Systems* (K222028), *IdentiTi™ and Transcend™ Interbody Systems* (K211805) and *Calibrate LTX Interbody Systems* (K223611).

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

An engineering analysis was utilized to determine that no new worst-case implants are being introduced compared to the predicate devices to support clearance of Calibrate LTX Interbody Systems. The engineering analysis demonstrates that the subject Calibrate LTX 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 device is substantially equivalent to legally marketed devices in regard to indications for use, intended use, design, technology, and performance.