



September 25, 2018

Alphatec Spine, Inc.
Mr. Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
5818 El Camino Real
Carlsbad, California 92008

Re: K181980

Trade/Device Name: OsseoScrew System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 24, 2018
Received: July 25, 2018

Dear Mr. Markovich:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181980

Device Name

OsseoScrew System

Indications for Use (Describe)

The OsseoScrew™ System (for use with the Zodiac™ Spinal Fixation System and Illico™ MIS Posterior Fixation System) is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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.

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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:

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Date Summary Prepared:

September 24, 2018

II. DEVICE

Name of Device: OsseoScrew System
Common or Usual Name: Orthosis, Spinal Pedicle Fixation
Classification Name: Thoracolumbosacral pedicle screw system
Regulation Number: 21 CFR 888.3070
Regulatory Class: Class II
Product Code: NKB

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate:

510(k)	Product Name	Clearance Date
K123623	Illico™ MIS Posterior Fixation System	February 14, 2013

Additional Predicates:

510(k)	Product Name	Clearance Date
K160879	CONFIDENCE™ High Viscosity Spinal Cement, VIPER® And EXPEDIUM® Fenestrated Screw Systems	December 20, 2016

IV. DEVICE DESCRIPTION

The OsseoScrew is a pedicle screw system that consists of pedicle screws and associated general instruments. Implant components are available in a variety of sizes to suit the individual pathology and anatomical conditions of the patient.

The subject cannulated polyaxial pedicle screws are in diameters of 6.5mm and 7.5mm with lengths ranging from 40 to 55mm. The OsseoScrew is designed to connect to 5.5mm

diameter rods and the associated components contained within the Zodiac Spinal Fixation System and the Illico MIS Posterior Spinal Fixation Systems.

The Alphatec Spine OsseoScrew System is an implantable pedicle screw device whose core is manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and the expandable screw shank is manufactured from CP2 Titanium conforming to ASTM F67 which are both industry recognized standards.

V. INDICATIONS FOR USE

The OsseoScrew™ System (for use with the Zodiac™ Spinal Fixation System and Illico™ MIS Posterior Fixation System) is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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. The different technological characteristics do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

Performance data and engineering analysis demonstrate that the subject OsseoScrew System is substantially equivalent to the predicates. Testing and analysis include static shank torsion, static shank tensile, dynamic shank bending, dynamic construct compression and static construct compression.

Clinical data on the subject device has been provided to support a substantial equivalence determination.

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.