October 15, 2020

Alphatec Spine, Inc.
Sandy Gill
Regulatory Affairs Associate
5818 El Camino Real
Carlsbad, California 92008

Re: K202327
Trade/Device Name: Invictus™ OsseoScrew® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 14, 2020
Received: August 17, 2020

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 (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,

for Colin O'Neill, M.B.E.
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)*
K202327

Device Name
Invictus™ OsseoScrew® System

Indications for Use *(Describe)*
The Invictus™ OsseoScrew® System (for use with the Invictus™ Spinal Fixation System and the transition rods from the Invictus™ CT Spinal 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.

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.
5818 El Camino Real
Carlsbad, CA 92008
Phone: (760) 431-9286
Fax: (760) 431-0289

Contact Person: Sandy Gill
Regulatory Affairs Associate
Contact Phone: (760) 431-9286

Date Summary Prepared: October 8, 2020

II. DEVICE

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

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K181980	NKB	OsseoScrew System	Alphatec Spine, Inc.
Additional Predicate Device			
K181677	NKB	Kodiak™ Spinal Fixation System	Alphatec Spine, Inc.
K192938	NKB	Invictus Spinal Fixation System	Alphatec Spine, Inc.
K982320	KWP	Moss Miami Spinal Fixation System	Depuy Motech

IV. DEVICE DESCRIPTION

The Invictus 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 6.5 mm and 7.5 mm with lengths ranging from 40 to 55 mm. The Invictus OsseoScrew is designed to be compatible with the

Invictus Spinal Fixation System screws, hooks, rods, connectors, and cross-connectors for the thoracolumbar spine and Invictus CT Spinal Fixation System for the cervical (C1 to C7) to thoracic (T1-T3) spine.

The Alphatec Spine Invictus 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 Invictus™ OsseoScrew® System (for use with the Invictus™ Spinal Fixation System and the transition rods from the Invictus™ CT Spinal 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.

VII. PERFORMANCE DATA

The following nonclinical testing was performed on the Invictus OsseoScrew System:

- ASTM F1717 static compression bending
- ASTM F1717 dynamic compression bending
- ASTM F1798 static A-P tulip pull-off (F_x) – straight shank orientation
- ASTM F1798 static A-P tulip pull-off (F_x) – angled shank orientation

The results demonstrate that the subject device is substantially equivalent to other predicate devices for nonclinical testing.

Clinical Information

Clinical data provided in K181980 to support a substantial equivalence determination is applicable to the subject device.

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.