December 18, 2020

Alphatec Spine, Inc.
Ruby Zheng
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K203125
Trade/Device Name: Invictus™ OCT Spinal Fixation System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: December 11, 2020
Received: December 14, 2020

Dear Ruby Zheng:

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,

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)*

K203125

Device Name
Invictus™ OCT Spinal Fixation System

Indications for Use *(Describe)*

The Invictus™ OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g.,pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Invictus OCT Spinal Fixation 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 advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Invictus OCT Spinal Fixation System may be connected to the components in the Arsenal® Spinal Fixation System or the Invictus™ Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

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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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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Regulatory Affairs Specialist
Contact Phone: (760) 494-6884

Date Summary Prepared: December 18, 2020

II. DEVICE

Name of Device:	Invictus™ OCT Spinal Fixation System
Common or Usual Name:	Posterior Cervical Screw System
Classification Name:	Posterior Cervical Screw System (21 CFR 888.3075)
Regulatory Class:	Class II
Product Code:	NKG

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K191185	NKG, KWP	Solanas® Posterior OCT Fixation System	Alphatec Spine
Additional Predicate Devices			
K200936	NKG	Invictus™ CT Spinal Fixation System	Alphatec Spine
K153631	NKG, KWP	Zimmer Virage® OCT Spinal Fixation System	Zimmer Spine
K161032	NKG, KWP	Neon3™ Universal OCT Spinal Stabilization	Alphatec Spine
K111076	NKG, KWP, MNI	Solanas Avalon Posterior Fixation System	Alphatec Spine
K093319	KWP	NuVasive® VuePoint® OCT System	Nuvasive
K200130	NKG, KWP	M.U.S.T. MINI Posterior Cervical Screws System	Medacta International SA

510(k)	Product Code	Trade Name	Manufacturer
K161363	NKB, KWP, MNH, MNI, OSH	Arsenal® Spinal Fixation System	Alphatec Spine
K192938	NKB.KWP	Invictus™ Spinal Fixation System	Alphatec Spine

IV. DEVICE DESCRIPTION

The purpose of this submission is to add occipital components to the previously cleared Invictus™ CT Spinal Fixation System (K200936). The Invictus™ OCT Spinal Fixation System is a posterior approach system designed to stabilize the cervico-thoracic spine and/or occiput with or without fusion. The Invictus OCT system is intended to be compatible with Arsenal® Spinal Fixation System or the Invictus™ Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

The Invictus OCT implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and cobalt chromium (Co-28Cr-6Mo) alloy per ASTM F1537. The Invictus OCT System consists of a variety of shapes and sizes of plates, screws, rods, cross connectors, rod-to-rod connectors and general surgical instruments that provide internal fixation and stabilization during bone graft healing and/or fusion mass development.

The Invictus OCT implants are provided non-sterile to be steam sterilized by the end user. The instruments are made of stainless steel and other materials, and are provided non-sterile to be cleaned and sterilized by the end user.

V. INDICATIONS FOR USE

The indications for use of the *Invictus™ OCT Spinal Fixation System* are identical to those of the predicate *Solanas® Posterior OCT Fixation* System:

The *Invictus™ OCT Spinal Fixation System* is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g.,pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The *Invictus OCT Spinal Fixation 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 advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the *Invictus OCT Spinal Fixation System* may be connected to the components in the *Arsenal® Spinal Fixation System* or the *Invictus™ Spinal Fixation System* offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

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 *Invictus OCT* system supports substantial equivalence to the predicate devices. The following testing was performed:

- Static and dynamic compression bending per ASTM F2706
- Static and dynamic torsion per ASTM F2706
- Static flexion-extension moment per ASTM F1798

The results demonstrate that the proposed Invictus OCT system is substantially equivalent to the 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.