June 3, 2019

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

Re: K191185
Trade/Device Name: Solanas® Posterior OCT Fixation System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: May 2, 2019
Received: May 3, 2019

Dear Ms. 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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K191185

Device Name
Solanas® Posterior OCT Fixation System

Indications for Use *(Describe)*
The Solanas Posterior OCT 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., pseudoarthorsis); 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 Solanas Posterior OCT 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 Solanas Posterior OCT Fixation System may be connected to the components in the Zodiac® Polyaxial Spinal Fixation System, the Arsenal® Spinal Fixation System, or the Invictus™ Spinal Fixation System offered by Alphatec Spine using the Rod to Rod Connectors 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 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) 431-6884
Fax: (760) 431-0289

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

Date Summary Prepared: May 2, 2019

II. DEVICE

Name of Device: Solanas® Posterior OCT Fixation System
Common or Usual Name: Occipital Cervical Thoracic System
Classification Name: Posterior Cervical Screw System (21 CFR 888.3075)
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)
Regulatory Class: Class II
Product Code: NKG, KWP

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K153631	NKG, KWP	Zimmer Virage OCT Spinal Fixation System	Zimmer Spine
Additional Predicate Device			
K173522	NKB, KWP	Solanas Posterior Stabilization System	Alphatec Spine

IV. DEVICE DESCRIPTION

The *Solanas Posterior OCT Fixation System* is a spinal fixation system intended to improve stability of the occipital, cervical, and thoracolumbar areas of the spine (Occiput-T3).

The *Solanas Posterior OCT Fixation System* is comprised of two sub-systems: a cervical thoracic system (Solanas®) and an occipital cervical thoracic system (Solanas® Avalon®) which share many of the same implants and instruments.

The implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and cobalt chromium (Co-28Cr-6Mo) alloy 1 (annealed and cold worked) and alloy 2 (warm worked) per ASTM F1537. The *Solanas Posterior OCT System* consists of a variety of shapes and sizes of screws, rods, hooks, bridges, connectors and general surgical instruments that provide temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. Since there have been no additional implants that were added to the system since last clearance in K173522, no additional mechanical testing is necessary in this submission.

The implants are provided non-sterile to be steam sterilized by the end user. The Class I general 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 *Solanas® Posterior OCT 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.,pseudoarthorsis); 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 *Solanas Posterior OCT 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 *Solanas Posterior OCT Fixation System* may be connected to the components in the *Zodiac® Polyaxial Spinal Fixation System*, the *Arsenal® Spinal Fixation System*, or the *Invictus® Spinal Fixation System* offered by Alphatec Spine using the Rod to Rod Connectors 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

The purpose of this 510(k) is to modify the Indications for Use for the subject *Solanas* system to include the use of bone screws in the cervical spine and include the system's use with other Alphatec Spine pedicle screw systems, i.e., Zodiac Spinal Fixation System, Arsenal Spinal Fixation System and Invictus Spinal Fixation System. Predicate submissions of the subject *Solanas Posterior OCT Fixation System* included performance testing and engineering analysis to assess the Static and Dynamic Compression Bending, Static and Dynamic Torsion and Axial Grip. Predicate submissions of the subject *Solanas Posterior OCT Fixation System* included performance testing and engineering analysis to assess the Static and Dynamic Compression Bending, Static and Dynamic Torsion and Axial Grip.. Since no new device designs and no new worst case sizes are being introduced to the *Solanas* system, the previously presented mechanical testing data in predicate K173522 is sufficient to support the expanded indications for the *Solanas* system.

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 regards to indications for use, intended use, design, technology, and performance.