December 15, 2021

Alphatec Spine, Inc.
Sandy Gill
Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K213443
Trade/Device Name: Insignia™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 22, 2021
Received: October 25, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213443

Device Name
Insignia™ Anterior Cervical Plate System

Indications for Use *(Describe)*
The Insignia™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

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

Date Summary Prepared: October 21, 2021

II. DEVICE

Name of Device:	Insignia™ Anterior Cervical Plate System
Common or Usual Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Regulatory Class:	Class II
Product Code:	KWQ

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K200995	KWQ	Insignia Anterior Cervical Plate System	Alphatec Spine, Inc.

IV. DEVICE DESCRIPTION

The *Insignia Anterior Cervical Plate System* is intended for anterior fixation to the cervical spine. The *Insignia Anterior Cervical Plate System* consists of a variety of sizes of plates and screws that are manufactured from titanium alloy conforming to ASTM F136 and are offered non-sterile. The instruments in this system are intended for use in surgical procedures. This submission seeks clearance for redesigned *Insignia* plates and screws.

V. INDICATIONS FOR USE

The Insignia™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

This submission introduces new Insignia plates and screws. 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 was presented on the *Insignia Anterior Cervical Plate System* using the performance criteria proposed in *Guidance for Industry and Food and Drug Administration Staff, Spinal Plating Systems- Performance Criteria for Safety and Performance Based Pathway*, issued on December 11, 2020. The following testing was performed in support of the subject devices:

- Static compression testing per ASTM F1717
- Static torsion testing per ASTM F1717
- Dynamic compression testing per ASTM F1717
- Screw push-out testing

The results demonstrate that the subject *Insignia Anterior Cervical Plate System* is 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 devices are substantially equivalent to legally marketed devices in regard to indications for use, intended use, design, technology, and performance.