August 28, 2025

Alphatec Spine, Inc.
Griffin Riggs
Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K251965
Trade/Device Name: Proximity™ Anterior Cervical Plate System; Segmental Plating System (SPS)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 25, 2025
Received: June 26, 2025

Dear Griffin Riggs:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MAZIAR SHAH-MOHAMMADI -S

[For] Brent Showalter, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251965

Please provide the device trade name(s).

Proximity™ Anterior Cervical Plate System;
Segmental Plating System (SPS)

Please provide your Indications for Use below.

Proximity™ Anterior Cervical Plate System
The Proximity 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.

Segmental Plating System
The Segmental Plating System (SPS) 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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.
1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 494-6860
Fax: (760) 431-0289

Contact Person: Griffin Riggs
Regulatory Affairs Specialist
Contact Phone: (760) 356-6796

Date Summary Prepared: August 28, 2025

II. DEVICE

Trade or Proprietary Name:	Proximity™ Anterior Cervical Plate System Segmental Plating System (SPS)
Common Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Name:	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number:	21 CFR 888.3060
Classification:	Class II
Product Code:	KWQ

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K213443	Insignia™ Anterior Cervical Plate System	KWQ	December 15, 2021

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K233640	Segmental Plating System	KWQ	February 22, 2024
K212446	NuVasive Anterior Cervical Plate Systems	KWQ	November 3, 2021

Reference Devices:

510(k)	Product Name	Product Code	Clearance Date
K192938	Invictus™ Spinal Fixation System	NKB, KWP	December 12, 2019
K161363	Arsenal™ Spinal Fixation System	NKB, KWP, NMH, MNI, OSH	June 10, 2016
K243461	Calibrate™ Interbody Systems	MAX	March 4, 2025

K241375	IdentiTi™ and Transcend™ Interbody Systems	MAX, OVD, PHM, ODP, OVE	February 3, 2025

IV. DEVICE DESCRIPTION

The subject *Alphatec Plating Systems* consists of two anterior cervical plate subsystems, *Proximity Anterior Cervical Plate System* and *Segmental Plating System*, intended for anterior fixation to the cervical spine. The *Alphatec Plating Systems* consist of a variety of sizes of plates and screws that are manufactured from titanium alloy conforming to ASTM F136. The systems offer instrumentation for the delivery of the plate and screw constructs. The instruments in this system are intended for use in surgical procedures. The *Alphatec Plating Systems* implants are provided either terminally sterile or non-sterile to be steam sterilized by the end user.

V. INDICATIONS FOR USE

Proximity™ Anterior Cervical Plate System

The Proximity™ 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.

Segmental Plating System (SPS)

The Segmental Plating System (SPS) 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

The technological design features of the subject *Alphatec Plating Systems* are substantially equivalent to the primary predicate *Insignia Anterior Cervical Plate System* (K213443) and the additional predicates: *Segmental Plating System* (K233640) and *NuVasive Anterior Cervical Plate Systems* (K212446).

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 non-clinical testing was performed and included, where appropriate for the design, or referenced in predicate 510(k) submissions to support clearance of *Alphatec Plating Systems*:

- ASTM F1717:2021 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
  - Static and Dynamic Compression Bending
  - Static Torsion
- Static Screw Push-out

Sterilization, packaging, and shelf-life validations were performed or adopted in accordance with ISO 11137-1, ISO 11137-2, ANSI/AAMI ST72, ISO 11607-1, and ISO 11607-2 to support sterile packaged *Alphatec Plating Systems* implants.

The results demonstrate that the subject *Alphatec Plating Systems* are substantially equivalent to other predicate devices for nonclinical testing.

VIII. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device is substantially equivalent to legally marketed devices in regard to indications for use, intended use, design, technology, and performance.