February 19, 2026

Alphatec Spine Inc.
Garima Shrivastava
Senior Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K252597
Trade/Device Name: Valence Robotic Navigation System; Valence Robotic Navigation Instruments (For Use with StealthStation)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 20, 2026
Received: January 20, 2026

Dear Garima Shrivastava:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252597

Device Name
Valence Robotic Navigation System; Valence Robotic Navigation Instruments (For Use with StealthStation)

Indications for Use *(Describe)*

Valence Robotic Navigation System:
Valence Robotic Navigation System is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan.

The Valence Robotic Navigation System is indicated for assisting surgeons in spinal procedures, such as:
• Pedicle screw placement
• Interbody device placement

Valence Robotic Navigation Instruments (for use with the StealthStation™):
The Valence Posterior Disc Prep Instruments are indicated to facilitate discectomy, bony resection, and implant selection during spinal surgery.

The Valence Posterior Fixation Instruments are intended to be used during the preparation and placement of Alphatec screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures.

Navigated instruments are specifically designed for use with the Medtronic® StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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.

A. SUBMITTER:

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Date Summary Prepared: August 15, 2025

B. DEVICE

Trade Name:	Valence Robotic Navigation System
Common or Usual Name:	Stereotaxic Instrument
Classification Name	Orthopedic stereotaxic instrument
Regulation Number:	21 CFR 882.4560
Regulatory Class:	Class II
Product Code:	OLO

LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate:

510(k)	Product Name	Product Code	Clearance Date
K232413	Fusion Robotic Navigation System	OLO	09/08/2023

Additional Predicates:

510(k)	Product Name	Product Code	Clearance Date
K161210	Medtronic Navigated Manual Reusable Instruments for use with the StealthStation™	OLO, OUR, HWE	08/12/2016
K232345	ATEC Posterior Navigated Disc Prep Instruments	OLO	11/02/2023
K240951	Invictus Robotic Navigation Instruments	OLO	06/06/2024
K200936	Invictus™ CT Spinal Fixation System	NKG	05/22/2020
K232275	Invictus® Spinal Fixation System	NKB, KWP, KWQ, OUR, PML	09/27/2023
K234092	SafeOp 3: Neural Informatix System	GWF, GXY, ETN, GXZ, PDQ, IKN	04/19/2024

Reference Devices:

510(k)	Product Name	Product Code	Clearance Date
K211616	ExcelsiusHub	OLO	08/25/2021
K192938	Invictus™ Spinal Fixation System	NKB, KWP	12/12/2019
K161363	Arsenal Spinal Fixation System	NKB, KWP, MNH, MNI, OSH	06/10/2016

DEVICE DESCRIPTION

The Valence Robotic Navigation System is an image guided system primarily comprised of a computer workstation, software, a trajectory system, including a targeting platform, a camera, and various image guided instruments intended for assisting the surgeon in placing pedicle screws and interbody implants in the thoracolumbar and sacral spine.

The system uses optical instrument tracking and registration to an intraoperative 3D scan to navigate patient anatomy across three independent workflows:

- Robotic assisted screw navigation
- Freehand screw navigation
- Freehand disc prep and interbody implant navigation

In addition to compatibility with the Valence Robotic Navigation System, select instruments referred to as Valence Robotic Navigation Instruments (for use with StealthStation™) are designed to be compatible with the Medtronic® StealthStation™ Surgical Navigation System. The navigated

disc preparation instruments are intended to facilitate discectomy, and bony resection while the posterior fixation instruments are intended to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants.

INDICATIONS FOR USE

Valence Robotic Navigation System

The Valence Robotic Navigation System is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan.

The Valence Robotic Navigation System is indicated for assisting surgeons in spinal procedures, such as:

- Pedicle screw placement
- Interbody device placement.

Valence Robotic Navigation Instruments (for Use with StealthStation™)

The Valence Posterior Disc Prep Instruments are indicated to facilitate discectomy, bony resection, and implant selection during spinal surgery.

The Valence Posterior Fixation Instruments are intended to be used during the preparation and placement of Alphatec screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures.

Navigation instruments are specifically designed for use with the Medtronic® StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

TECHNOLOGICAL COMPARISON TO PREDICATE

The subject device Valence Robotic Navigation System is substantially equivalent to the primary predicate, Fusion Robotic Navigation System (K232413). Additionally, the subject Valence Robotic Navigation Instruments (for use with Stealth Station) are substantially equivalent to Medtronic Navigated Manual Reusable Instruments for use with the StealthStation™ (K161210) and ATEC Posterior Navigated Disc Prep Instruments (K232345). The technological design features of the subject device were compared to the predicate devices in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent. Any technological differences within this 510(k), between the subject device and the predicate device, does not impact substantial equivalence, or safety and effectiveness.

PERFORMANCE DATA

The following nonclinical performance tests were performed to support the substantial equivalence of the subject Valence Robotic Navigation System to its predicates:

- Software Verification
- Hardware Verification
- Accuracy Verification Testing
- Dimensional analysis of the Valence Instruments for Use with StealthStation compared to Medtronic instruments
- Simulated use testing using cadaveric specimens

The results of these tests demonstrate that the subject Valence Robotic Navigation System is substantially equivalent to the primary predicate Fusion Robotic Navigation System (K232413) and additional predicates Medtronic Navigated Manual Reusable Instruments for use with the StealthStation™ (K161210) and ATEC Posterior Navigated Disc Prep Instruments (K232345).

CONCLUSION

The information provided in this submission, and in the discussion in ***Section 3***, ***Substantial Equivalence***, demonstrates that the subject device does not pose additional risk to safety and effectiveness when compared to the predicate device. The subject device Valence Robotic Navigation System is substantially equivalent to the primary predicate, Fusion Robotic Navigation System (K232413) and additional predicates, ATEC Posterior Navigated Disc Prep Instruments (K232345) and Medtronic Navigated Manual Reusable Instruments for use with the StealthStation™ (K216120).