



November 2, 2023

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

Re: K232345

Trade/Device Name: ATEC Posterior Navigated Disc Prep Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 4, 2023
Received: August 4, 2023

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 (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.

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,

Tejen D. Soni -S

For
Shumaya Ali, MPH
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

Indications for Use

510(k) Number (if known)
K232345

Device Name
ATEC Posterior Navigated Disc Prep Instruments

Indications for Use (Describe)

The ATEC Posterior Navigated Disc Prep Instruments are indicated to facilitate discectomy, bony resection, implant selection, and access during spinal surgery. 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 section applies only to requirements of the Paperwork Reduction Act of 1995.

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K232345
510(k) Summary



Traditional 510(k) Premarket Notification
ATEC Posterior Navigated Disc Prep Instruments

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) 431-9286
Fax: (760) 431-0289

Contact Person: Sandy Gill
Manager, Regulatory Affairs

Date Summary Prepared: November 1, 2023

II. DEVICE

Trade or Proprietary Name: ATEC Posterior Navigated Disc Prep Instruments
Common Name: Navigation Instruments
Classification Name: Orthopedic Stereotaxic Instrument
Regulation Number: 21 CFR 882.4560
Classification: Class II
Product Code: OLO

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Clearance Date
K201267	Adaptix Interbody System with Titan nanoLOCK Surface Technology Navigated Disc Prep Instruments including Navigated Rotating Shavers	August 26, 2020

Additional Predicate Device:

510(k)	Product Name	Clearance Date
K211441	Navigated Anterolateral Disc Prep Instruments	June 09, 2021

Reference Devices:

510(k)	Product Name	Clearance Date
K161363	Arsenal Spinal Fixation System	June 10, 2016
K203056	Invictus Spinal Fixation System	November 23, 2020
K200719	NuVasive Navigation.S Instruments	December 02, 2020
K223765	ATEC Lateral Navigation Instruments	March 23, 2023

IV. DEVICE DESCRIPTION

The *ATEC Posterior Navigated Disc Prep Instruments* are surgical instruments that 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. The navigated trials are intended to facilitate implant size selection of Alphatec intervertebral body fusion devices during spinal surgery. All instruments are reusable and are offered non-sterile to be cleaned and steam sterilized by the end user.

V. INDICATIONS FOR USE

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

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject instruments were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.

Clinical Information

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

VII. PERFORMANCE DATA

The following performance testing was conducted on the subject *ATEC Posterior Navigated Disc Prep Instruments*:

- Dimensional analysis of the instruments compared to Medtronic instruments
- Testing to confirm performance and safety of the subject instruments when used with Medtronic StealthStation System.

Testing results demonstrated the subject *ATEC Posterior Navigated Disc Prep Instruments* are substantially equivalent when compared to other legally marketed devices cleared by FDA.

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.