March 23, 2023

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

Re: K223765
Trade/Device Name: ATEC Lateral Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 17, 2023
Received: February 21, 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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223765

Device Name

ATEC Lateral Navigation Instruments

Indications for Use *(Describe)*

The ATEC Lateral Navigation Instruments are intended to facilitate discectomy, boney 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. The Stimulating Initial Dilator may also be utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Date Summary Prepared: March 23, 2023

II. DEVICE

Trade or Proprietary Name:	ATEC Lateral Navigation 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
K192336	Navigated Anterolateral Disc Prep Instruments	November 22, 2019

Additional Predicate Devices:

510(k)	Product Name	Clearance Date
K221821	ATEC IOM Accessory Instruments	September 23, 2022
K200719	NuVasive Navigation Instruments	December 2, 2020

IV. DEVICE DESCRIPTION

The *ATEC Lateral Navigation Instruments* are surgical instruments that are designed to be compatible with Medtronic's StealthStation Surgical Navigation System. The navigated disc preparation and dilator instruments are intended to facilitate discectomy, boney resection, access, and nerve location during spinal surgery. The navigated trials are intended to facilitate implant size selection of Alphatec intervertebral body fusion devices during spinal surgery. All instruments are reusable or single-use and are offered either non-sterile to be cleaned and steam sterilized by the end user or sterile packaged.

V. INDICATIONS FOR USE

The ATEC Lateral Navigation Instruments are intended to facilitate discectomy, boney 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. The Stimulating Initial Dilator may also be utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

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 Lateral Navigation 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 Lateral Navigation 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.