



Food and Drug Administration
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Alphatec Spine, Incorporated
Ms. Renée Murphy
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

April 29, 2016

Re: K153603

Trade/Device Name: Alphatec Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 15, 2015
Received: December 17, 2015

Dear Ms. Murphy:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K153603

Device Name

Alphatec Navigation Surgical Instruments

Indications for Use (Describe)

Alphatec Spine Navigated Reusable 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. Alphatec Spine Navigated Reusable 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 a skull, along bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.”

510(k) Summary

I. SUBMITTER

Alphatec Spine, Inc.
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Contact Person: Renée L. Murphy
Date Prepared: March 24, 2016

II. DEVICE

Name of Device: Alphatec Spine Navigation Instruments
Common or Usual Name: Stereotaxic instruments
Classification Name: Stereotaxic instruments (21 CFR 882.4560)
Regulatory Class: II
Product Code: OLO

III. PREDICATE DEVICE

K140454, Medtronic Navigation, Inc., Navigated CD Horizon Solera Screwdrivers and Taps

IV. DEVICE DESCRIPTION

The Alphatec NAV Instruments are Class II, manual, surgical instruments for use with Medtronic StealthStation Navigation system 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. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

The purpose of this Traditional 510(k) Premarket Notification is to clear for market Alphatec NAV Instruments which are additions to the Arsenal™ Spinal Fixation System (K133221, K143149, K152968) and the Illico MIS® Posterior Fixation System (K123623) for use with the Medtronic StealthStation System.

V. INDICATIONS FOR USE

Alphatec Spine Navigated Reusable 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. Alphatec Spine Navigated Reusable 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 a skull, along bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject Alphatec Spine Navigation Instruments were compared to the predicate in indications for use, intended use, design, technology, materials, function, and performance. It was demonstrated that the subject Alphatec NAV Instrument technology is substantially equivalent to the predicate.

VII. PERFORMANCE DATA

Engineering analysis and performance data demonstrate that the subject Alphatec Spine Navigation Instruments are substantially equivalent to the predicate in compatibility, accuracy, function, and performance. Engineering analysis includes dimensional measurements of both predicate and subject devices. Verification testing includes interface compatibility and functionality of the subject device. Validation testing includes 1:1 accuracy and performance testing of the subject and predicate device in a simulated surgical navigation use environment.

Therefore, it can be concluded that the compatibility, accuracy, function, and performance of the subject Alphatec NAV Instruments are substantially equivalent to the predicate Medtronic navigation instruments when used with the StealthStation System and NavLock Tracker.

VIII. CONCLUSION

Based upon the information provided in this Traditional 510(k) submission, it has been demonstrated that the subject Alphatec Spine Navigation Instruments are substantially equivalent to legally marketed predicate devices in regards to indications for use, intended use, design, technology, functionality, and performance.