September 8, 2023

Alphatec Spine, Inc.
Sarah Braun
Senior Regulatory Affairs Specialist
168 Centennial Parkway, Unit 170
Louisville, Colorado 80027

Re: K232413
Trade/Device Name: Fusion Robotic Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 10, 2023
Received: August 10, 2023

Dear Sarah Braun:

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,

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

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)*
K232413

Device Name
Fusion Robotic Navigation System

Indications for Use *(Describe)*
The Fusion 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 Fusion Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the ATEC Invictus® Spinal Fixation System.

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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This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner	Alphatec Spine, Inc. 1950 Camino Vida Roble Carlsbad, CA 92008
Contact Person	Sarah Braun Senior Regulatory Affairs Specialist Tel: 423-838-4454 Email: sbraun@atecspine.com
Date Prepared	September 8, 2023
Classification Reference	21 CFR 882.4560
Product Code	OLO
Common/Usual Name	Stereotaxic Instrument
Trade/Proprietary Name	Fusion Robotic Navigation System
Primary Predicate Device(s)	REMI Robotic Navigation System (K223070)
Additional Predicate Device	Accelus LineSider Navigation Instruments (K231098)

The Fusion 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 screws in the pedicles of the lumbar spine.

Indications for Use

The Fusion 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 Fusion Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the ATEC Invictus® Spinal Fixation System.

Comparison of the Technological Characteristics

The proposed Fusion Robotic Navigation System is considered substantially equivalent to the REMI Robotic Navigation System (K223070). The only change to the indications for use is the replacement of Accelus LineSider with ATEC Invictus® Spinal Fixation System. The IFU is also updated with the addition of the Invictus Guide Tube, Invictus 8mm Guide Tube Sleeve and Invictus MIS Driver. The principles of operation, mode of operation, and performance are the same as the predicate.

Additional Instruments

To facilitate the use of the ATEC Invictus® Spinal Fixation System with the Fusion Robotic Navigation System three additional instruments were added: the Invictus Guide Tube (P1012), Invictus 8mm Guide Tube Sleeve (P1021), and Invictus MIS Screwdriver (P1067). All of these instruments are manufactured from the same materials used in the predicate system and also follow the same manufacturing processes.

The new instruments do not introduce a worst case for biocompatibility, cleaning, or sterilization. No new risks were identified, and no existing risks were impacted by the addition of the Invictus® Spinal Fixation System instruments. No requirements were added to the design requirements document as a part of this change. The design requirements document was updated to standardize nomenclature for existing instrumentation and replace "Remi" with "SGS" (Surgical Guidance System) where appropriate. Other minor clerical changes were made to the design requirements document.

Performance Testing

An engineering analysis was conducted comparing the Invictus Guide Tube, Invictus 8mm Guide Tube Sleeve and Invictus MIS to the predicate Guide Tube, 8mm Guide Tube Sleeve and MIS Driver. Invictus® Spinal Fixation System instruments maintain all the same critical features as the predicate designs. The stackup of the tolerances do not create any new worst-case conditions. The Invictus® Spinal Fixation System instruments are used in an identical manner to the predicate versions using the same software.

The results of this engineering analysis show that the Invictus® Spinal Fixation System instruments are substantially equivalent to the predicate. Therefore, no additional verification and validation testing is required.

Conclusion

The subject device, Fusion Robotic Navigation System, described in this submission has the same intended use and the same technological characteristics as the predicate device, REMI Robotic Navigation System (K223070). The primary difference between the subject device and the predicate is the use with the Invictus® Spinal Fixation System and the introduction of Invictus® Spinal Fixation System instruments.

The engineering analysis performed on the new instrumentation demonstrated that the characteristics of the subject Fusion Robotic Navigation System is substantially equivalent to the predicate device. The subject device continues to meet design requirements, is as safe and effective as the predicate device, and performs according to its intended use. The information presented in this 510(k) premarket notification demonstrates that the subject device is substantially equivalent to the predicate REMI Robotic Navigation System (K223070).