October 6, 2023

Alphatec Spine, Inc.
Unnati Bhuptani
Sr. Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K232044
Trade/Device Name: Invictus Robotic Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 6, 2023
Received: July 10, 2023

Dear Unnati Bhuptani:

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,

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.

Submission Number *(if known)*

K232044

Device Name

Invictus Robotic Navigation Instruments

Indications for Use *(Describe)*

The Invictus Robotic Navigation Instruments are indicated for use during the placement of Invictus Spinal Fixation System modular screws in either open or minimally invasive procedures. The Invictus Robotic Navigation Instruments are specifically designed for use with Globus Medical's Excelsius GPS® Robotic Navigation Platform, which is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures, provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

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.

K232044

510(k) Summary

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

Contact Person: Unnati Bhuptani
Sr. Regulatory Affairs Specialist

Date Summary Prepared: September 12, 2023

II. DEVICE

Trade or Proprietary Name:	Invictus Robotic 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
K220862	E-GPS Navigated Instruments	July 14, 2022

Additional Predicate Devices:

510(k)	Product Name	Clearance Date
K171651	EXCELSIUS GPS®	August 16, 2017
K221926	Invictus® Bone Cement, Invictus Spinal Fixation System	December 20, 2022

Reference Devices:

510(k)	Product Name	Clearance Date
K161363	Arsenal Spinal Fixation System	June 10, 2016

IV. DEVICE DESCRIPTION

The *Invictus Robotic Navigation Instruments* are surgical instruments that is designed to be compatible with Globus Medical's Excelsius GPS® Robotic Navigation Platform. The subject device is intended to facilitate the placement of screws during spinal surgery. The subject device are reusable instruments and offered non-sterile to be cleaned and steam sterilized by the end user.

V. INDICATIONS FOR USE

The Invictus Robotic Navigation Instruments are indicated for use during the placement of Invictus Spinal Fixation System modular screws in either open or minimally invasive procedures. The Invictus Robotic Navigation Instruments are specifically designed for use with Globus Medical's Excelsius GPS® Robotic Navigation Platform, which is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures, provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The subject Invictus Robotic Navigation Instruments have equivalent technological characteristics to that of the predicate devices and the minor differences do not raise any new issues of the safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Device design and dimensions
- Indications for Use
- Materials of manufacture
- Principles of Operation

Identical to the predicates, the subject Invictus Robotic Navigation Instruments are also non-sterile, reusable instruments to be steam sterilized by the end user.

The technological design features of the subject instrument 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 *Invictus Robotic Navigation Instruments* have been evaluated through a dimensional analysis and geometric comparison to the predicate devices to establish the safety and effectiveness for accuracy performance.

The subject *Invictus Robotic Navigation Instruments* were compared to the predicate/reference devices and found to be substantially equivalent to the predicate/reference devices in terms of cleaning and reprocessing.

The results of this engineering analysis show that the subject is substantially equivalent to the cleared predicate.

VIII. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device is substantially equivalent to legally marketed devices in regard to indications for use, intended use, design, technology, and performance.