June 21, 2024

Alphatec Spine, Inc.
Andrew Zhang
Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K241519
Trade/Device Name: Invictus® Small Stature Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: May 24, 2024
Received: May 29, 2024

Dear Andrew Zhang:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K241519

Device Name
Invictus® Small Stature Spinal Fixation System

Indications for Use *(Describe)*
The Invictus® Small Stature Spinal Fixation System is intended for non-cervical posterior and anterolateral fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.
When used for posterior non-cervical screw fixation in pediatric patients, the Invictus® Small Stature Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Invictus® Small Stature Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.
The Invictus® Small Stature Spinal Fixation System is intended to be used with autograft and/or allograft.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 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) 494-6860
Fax: (760) 431-0289

Contact Person: Andrew Zhang
Regulatory Affairs Specialist
Contact Phone: (760) 494-6860

Date Summary Prepared: June 21, 2024

II. DEVICE

Trade or Proprietary Name:	Invictus® Small Stature Spinal Fixation System
Common Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System, Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis
Regulation Number:	21 CFR 888.3070, 888.3050, 888.3060
Classification:	Class II
Product Code:	NKB, KWP, KWQ

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K232275	Invictus® Spinal Fixation System	NKB, KWP, KWQ, PML, OUR	September 27, 2023

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K223181	NuVasive Reline System	NKB, KWP, KWQ	January 11, 2023
K161363	Arsenal™ Spinal Fixation System	NKB, OSH, MNI, MNH, KWP	June 10, 2016
K113395	REVERE 4.5 Stabilization System	MNH, MNI, KWQ, KWP, NKB, OSH	June 14, 2012
K181390	Response Spine System, Response 5.5/6.0 Spine System, Response 4.5/5.0 Spine System	NKB, KWP	September 18, 2018
K192938	Invictus® Spinal Fixation System	NKB, KWP	December 12, 2019

IV. DEVICE DESCRIPTION

The Invictus® Small Stature Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The Invictus® Small Stature Spinal Fixation system is compatible with Arsenal® Spinal Fixation System and Invictus® Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods. The Invictus® Small Stature Spinal Fixation System consists of a variety of shapes and sizes of rods, screws, hooks, connectors, and cross connectors that provide internal fixation and stabilization during bone graft healing and/or fusion mass development. The screws, hooks, connectors, and cross connectors are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The rods are available in commercially pure titanium (CP Ti Grade 4) per ASTM F67, titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and cobalt chrome (Co-28Cr-6Mo) per ASTM F1537.

The Invictus® Small Stature implants are provided non-sterile to be steam sterilized by the end user. The instruments are made of stainless steel and other materials and are provided non-sterile to be cleaned and sterilized by the end user. The instruments in this system are intended for use in surgical procedures.

V. INDICATIONS FOR USE

The Invictus® Small Stature Spinal Fixation System is intended for non-cervical posterior and anterolateral fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, the Invictus® Small Stature Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Invictus® Small Stature Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The Invictus® Small Stature Spinal Fixation System is intended to be used with autograft and/or allograft.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject *Invictus Small Stature Spinal Fixation System* is substantially equivalent to the primary predicate *Invictus Spinal Fixation System*

(K232275), and additional predicates *NuVasive Reline System* (K223181) and *Arsenal Spinal Fixation System* (K152968).

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

VII. PERFORMANCE DATA

The following non-clinical testing was performed and included, where appropriate for the design, or referenced in predicate 510(k) submissions to support clearance of Invictus Small Stature Spinal Fixation System:

- ASTM F1717 Static Compression Bending
- ASTM F1717 Dynamic Compression Bending
- ASTM F1798 Static A-P Tulip Pull-off (*Fx*) – Straight
- ASTM F1798 Static A-P Tulip Pull-off (*Fx*) – Angled
- F1798 Static Flexion-Extension (My) – Bottom-loading, Straight
- F1798 Static Flexion-Extension (My) – Bottom-loading, Angled

The results demonstrate that the subject *Invictus Small Stature Spinal Fixation System* is substantially equivalent to other predicate devices for nonclinical testing.

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.