July 14, 2026

Alphatec Spine, Inc.
Andrew Zhang
Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92084

Re: K261284
Trade/Device Name: Invictus® Small Stature Spinal Fixation System; Invictus® 2.0 Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, PML, OUR, OLO
Dated: April 17, 2026
Received: April 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261284 ?

Please provide the device trade name(s). ?

Invictus® Small Stature Spinal Fixation System;
Invictus® 2.0 Spinal Fixation System

Please provide your Indications for Use below. ?

Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System
The Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System are 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 and Invictus 2.0 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 and Invictus 2.0 Spinal Fixation System are 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 and Invictus 2.0 Spinal Fixation System are intended to be used with autograft and/or allograft.

Invictus Small Stature/Invictus 2.0 SI.CORE Screws are intended to be used with Alphatec's 4.5, 5.0, 5.5 and 6.0 mm diameter rods for sacroiliac joint fusion for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Invictus Small Stature/Invictus 2.0 CORE and Invictus Small Stature/Invictus 2.0 SI.CORE Screws are not intended for use with cement; all other fenestrated screws may be used with Invictus Bone Cement. When used in conjunction with Invictus Bone Cement, the Invictus Small Stature/Invictus 2.0 Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Invictus Small Stature/Invictus 2.0 Fenestrated Screws augmented with Invictus Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Invictus 2.0 Navigation Instruments (for Use with StealthStation™)
The Invictus 2.0 Navigation Instruments are intended to be used during the placement of Alphatec screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or

minimally invasive, procedures.

Navigation 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)	?

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
Carlsbad, CA 92008
Phone: (760) 494-6860
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Contact Person: Andrew Zhang
Regulatory Affairs Specialist
Contact Phone: (760) 494-6860

Date Summary Prepared: April 16, 2026

II. DEVICE

Trade or Proprietary Name:	Invictus® Small Stature Spinal Fixation System; Invictus® 2.0 Spinal Fixation System
Common Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System Spinal Interlaminal Fixation Orthosis Spinal Intervertebral Body Fixation Orthosis Polymethylmethacrylate (PMMA) bone cement Spinal Intervertebral Body Fixation Orthosis Stereotaxic Instrument
Regulation Number:	21 CFR 888.3070, 21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3027, 21 CFR 888.3040, 21 CFR 882.4560
Classification:	Class II
Product Code:	NKB, KWP, KWQ, PML, OUR, OLO

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
K241519	Invictus® Small Stature Spinal Fixation System	NKB, KWP, KWQ	June 21, 2024
K180337	EUROPA™ Pedicle Screw System	NKB	March 14, 2019

K161210	Medtronic Navigated Manual Reusable Instruments for use with the StealthStation™	OUR, HWE, OLO	August 12, 2016
K252597	Valence Robotic Navigation Instruments (for use with StealthStation)	OLO	February 19, 2026

IV. DEVICE DESCRIPTION

The Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System are 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 and Invictus 2.0 Spinal Fixation System are compatible with the Invictus Spinal Fixation System and Arsenal Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods. The Invictus Small Stature Spinal Fixation system and Invictus 2.0 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, cobalt chrome (Co-28Cr-6Mo) per ASTM F1537, and Molybdenum-47.5Rhenium alloy per ASTM F3273-17.

Invictus Small Stature/Invictus 2.0 SI.CORE bone screws are intended to provide sacroiliac joint fusion in sacral alar iliac (SAI) trajectories. Invictus Small Stature/Invictus 2.0 CORE and Invictus Small Stature/Invictus 2.0 SI.CORE Screws are not intended for use with cement; all other fenestrated screws may be used with Invictus Bone Cement, a self-hardening and ready to use polymethylmethacrylate (PMMA) bone cement with a high amount of radiopaque agent.

The Invictus Small Stature Patient Specific Rods are used to connect pedicle screws, hooks, and connectors across different levels of vertebral bodies to create a rigid construct. They are intended to be used with standard Invictus Small Stature instrumentation. The Invictus Small Stature Patient Specific Rods are available in Ø4.5 mm and 5.0 mm diameters and will be provided in lengths between 20 - 600 mm. Equivalent to cleared Invictus Small Stature rod materials, the rods are made from: 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. All Invictus Small Stature Patient Specific Rods are provided pre-contoured to the surgeon's plan based on the patient's anatomy by means of an industrial bending process prior to distribution for surgery.

The Invictus 2.0 Navigation Instruments (for use with StealthStation™) are designed to be compatible with the Medtronic® StealthStation™ Surgical Navigation System. The navigated instruments are intended to be used during the placement of Alphatec screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures.

The Invictus Small Stature and Invictus 2.0 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

Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System

The Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System are 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 and Invictus 2.0 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 and Invictus 2.0 Spinal Fixation System are 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 and Invictus 2.0 Spinal Fixation System are intended to be used with autograft and/or allograft.

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- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Invictus Small Stature/Invictus 2.0 CORE and Invictus Small Stature/Invictus 2.0 SI.CORE Screws are not intended for use with cement; all other fenestrated screws may be used with Invictus Bone Cement. When used in conjunction with Invictus Bone Cement, the Invictus Small Stature and Invictus 2.0 Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Invictus Small Stature and Invictus 2.0 Fenestrated Screws augmented with Invictus Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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Navigation 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.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject *Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System* are substantially equivalent to the primary predicate *Invictus Spinal Fixation System* (K232275), and additional predicates *Invictus Small Stature Spinal Fixation System* (K241519), *EUROPA Pedicle Screw System* (K180337), *Medtronic Navigated Manual Reusable Instruments for use with the StealthStation* (K161210) and *Valence Robotic Navigation Instruments (for use with StealthStation)* (K252597).

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 and Invictus 2.0 Spinal Fixation System:

- ASTM F1717 Static Compression Bending
- ASTM F1717 Dynamic Compression Bending
- ASTM F1798 Static A-P Tulip Pull-off (*Fx*) – Straight and Angled Shank Orientations
- ASTM F1798 Axial Gripping Capacity (*Fz*)
- ASTM F1877 Particulate Analysis
- ASTM F2129 Pitting Corrosion
- ASTM F3044 Galvanic Corrosion
- ASTM F1798 Static Flexion-Extension (*My*) – Straight and Angled Shank Orientations
- ASTM F1798 Dynamic Flexion-Extension (*My*)
- Dimensional Analysis of the Invictus 2.0 Navigation Instruments for Use with StealthStation compared to Medtronic instruments

The results demonstrate that the subject *Invictus Small Stature Spinal Fixation System and Invictus 2.0 Spinal Fixation System* are 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.