



December 20, 2022

Alphatec Spine, Inc.  
Aditya Aiyer  
Regulatory Affairs Specialist  
1950 Camino Vide Roble  
Carlsbad, California 92008

Re: K221926

Trade/Device Name: Invictus® Bone Cement, Invictus Spinal Fixation System  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement  
Regulatory Class: Class II  
Product Code: PML, NKB, KWP, KWQ  
Dated: November 29, 2022  
Received: November 30, 2022

Dear Aditya Aiyer:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anne D. Talley -S for

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

510(k) Number (if known)  
K221926

Device Name  
Invictus® Bone Cement, Invictus Spinal Fixation System

### Indications for Use (Describe)

The Invictus 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 pedicle screw fixation in pediatric patients, the Invictus 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 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 Spinal Fixation System is intended to be used with autograft and/or allograft.

Invictus Core and Invictus 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 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 Fenestrated Screws augmented with Invictus Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

**I. SUBMITTER:** Alphatec Spine, Inc.  
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Regulatory Affairs Specialist  
Contact Phone: (760) 494-6671

Date Summary Prepared: December 19, 2022

## II. DEVICE

Name of Device: Invictus® Bone Cement, Invictus Spinal Fixation System

Common or Usual Name: Bone cement, Thoracolumbosacral pedicle screw system, Spinal Interlaminar Fixation System, Spinal Intervertebral Body Fixation System

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement (21 CFR 888.3027) Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070) Spinal Interlaminar Fixation Orthosis (21 CFR 888.3050) Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

Regulatory Class: Class II

Product Code: PML, NKB, KWP, KWQ

## III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
<b>Primary Predicate Device</b>			
K103433	NDN	F20	Teknimed
<b>Additional Predicate Devices</b>			
K214006	NKB, KWP	Invictus® Spinal Fixation System	Alphatec Spine
K200596	PML, NKB	G21 Cement, VADER Pedicle System	Icotec AG
K173095	NKB, KWP, KWQ	VIPER PRIME™ Screws, VIPER PRIME™ Screws with Fenestrations, EXPEDIUM® Verse Screws with Fenestrations	DePuy Synthes



510(k)	Product Code	Trade Name	Manufacturer
K212692	NKB, KWQ, KWP	Mariner Pedicle Screw System	SeaSpine
K180498	PML, NKB, KWP	High V+ Bone Cement, NuVasive® Reline® Fenestrated Screws	NuVasive

#### IV. DEVICE DESCRIPTION

The *Invictus Spinal Fixation System* is thoracolumbosacral spinal fixation system designed to be implanted through a non-cervical posterior or anterolateral surgical approach. The implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, commercially pure titanium (CP Ti Grade 2) per ASTM F67 and cobalt chromium (Co-28Cr-6Mo) alloy per ASTM F1537. The Invictus System consists of a variety of shapes and sizes of screws, hooks, rods, connectors, and cross-connectors to create a rigid construct as an adjunct to fusion for temporary internal fixation and stabilization of the thoracic, lumbar and sacral spine.

*Invictus Bone Cement* is a self-hardening and ready to use polymethylmethacrylate (PMMA) bone cement with a high amount of radiopaque agent for percutaneous vertebroplasty. The cement is made of two sterile components: the polymer in powder and the liquid monomer. The liquid component is mainly composed of methyl methacrylate. The major powder components are polymethylmethacrylate, methyl methacrylate, and zirconium dioxide. Benzoyl peroxide, which initiates polymerization, is included in the polymer powder. The powder and liquid monomer are in a double sterile packaging. Each unit contains a sterile ampoule of liquid within a blister pack and a powder within a double peelable pouch, the whole being packaged in a box.

The purpose of this submission is to expand indications for use of Invictus fenestrated screws with Invictus Bone Cement, add new fixed fenestrated pedicle screws to the Invictus Spinal Fixation System, and to expand indications of the Invictus Spinal Fixation System for non-cervical anterolateral fixation.

#### V. INDICATIONS FOR USE

The Invictus 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 pedicle screw fixation in pediatric patients, the Invictus 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



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.

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## VI. TECHNOLOGICAL COMPARISON TO PREDICATES

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

Nonclinical testing performed on the subject *Invictus Bone Cement, Invictus Spinal Fixation System*, supports substantial equivalence to the other predicate devices. The following testing was performed:

- Axial Pullout Strength testing per ASTM F543
- Screw Torque Removal testing per ASTM F543
- Cadaveric testing to evaluate cement flow and bolus formation

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

### **Clinical Information**

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

## VIII. CONCLUSION

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