Alphatec Spine, Inc.
Cynthia Dorne
Sr. Manager, Regulatory Affairs
1950 Camino Vida Roble
Carlsbad, California 92008

September 27, 2023

Re: K232275
Trade/Device Name: Invictus® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, PML, KWQ, OUR
Dated: July 28, 2023
Received: July 31, 2023

Dear Cynthia Dorne:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.09.27 16:41:07 -04'00'

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

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)*
K232275

Device Name
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 SI.CORE Screws are intended 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 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:

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1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 431-9286
Fax: (760) 431-0289

Contact Person: Cynthia Dorne
Sr. Manager, Regulatory Affairs
Contact Phone: (760) 494-6740

Date Summary Prepared: July 28, 2023

II. DEVICE

Name of Device: Invictus® Spinal Fixation System

Common or Usual Name:
Thoracolumbosacral Pedicle Screw System
Spinal Interlaminal Fixation System
Bone Cement
Metallic Bone Fixation Fastener

Classification Name:
Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)
Polymethylmethacrylate (PMMA) bone cement (21 CFR 888.3027)
Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)

Regulatory Class: Class II

Product Code: NKB, KWP, PML, KWQ, OUR

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K222774	OUR, NKB, OLO	iFuse Bedrock Granite Implant System	SI-BONE
Additional Predicate Devices			
K221926	OUR, NKB, KWP, PML, KWQ	Invictus® Bone Cement, Invictus Spinal Fixation System	Alphatec Spine

510(k)	Product Code	Trade Name	Manufacturer
K140738	MNI, MNH, KWP, OSH	Pass LP Spinal System	Medicrea International

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 SI.CORE bone screws are intended to provide sacroiliac joint fusion in sacral alar iliac (SAI) trajectories. 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, a self-hardening and ready to use polymethylmethacrylate (PMMA) bone cement with a high amount of radiopaque agent for percutaneous vertebroplasty.

The Invictus 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 instrumentation. The Invictus Patient Specific Rods are available in Ø5.5 mm and 6.0 mm diameters and will be provided in lengths between 20 - 600 mm. Equivalent to cleared Invictus rod materials, the rods are made from five different materials: Commercially Pure Titanium (CP Ti Grade 4), Titanium Alloy (Ti-6Al-4V ELI), and three different formulations of Cobalt Chromium (Co-28Cr-6Mo). All *Invictus* 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. There is no need for additional bending during surgery.

The purpose of this submission is to expand indications for use of Invictus SI.CORE screws as sacroiliac joint fusion devices, and to add a range of Invictus Patient-Specific Rods to the Invictus Spinal Fixation System.

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.

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

Invictus SI.CORE Screws are intended for sacroiliac joint fusion for the following conditions:

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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.

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

Engineering analysis and rationale was provided to demonstrate that the subject Invictus Spinal Fixation System is substantially equivalent to the predicate Invictus Spinal Fixation System.

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.