March 25, 2026

Alphatec Spine, Inc.
Griffin Riggs
Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K253615
Trade/Device Name: Invictus® Bands System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: March 3, 2026
Received: March 3, 2026

Dear Griffin Riggs:

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,

MAZIAR SHAH-MOHAMMADI -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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253615

Please provide the device trade name(s).

Invictus® Bands System

Please provide your Indications for Use below.

The Invictus® Bands System consists of temporary implants for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;
- Use with a posterior spinal instrumentation construct when ligament augmentation is needed.

The Invictus® Bands System may also be used in conjunction with other medical implants made of commercially pure titanium, titanium alloy, or cobalt chrome whenever “wiring” may help secure the attachment of other implants.

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)

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

Contact Person: Griffin Riggs
Regulatory Affairs Specialist
Contact Phone: (760) 356-6796

Date Summary Prepared: November 17, 2025

II. DEVICE

Trade or Proprietary Name:	Invictus® Bands System
Common Name:	Bone Fixation Cerclage
Classification Name:	Bone Fixation Cerclage, Sublaminar
Regulation Number:	21 CFR 888.3010
Classification:	Class II
Product Code:	OWI

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Product Code	Clearance Date
K213659	LigaPASS™ 2.0 Ligament Augmentation System	OWI	May 24, 2022

Additional Predicate Devices:

510(k)	Product Name	Product Code	Clearance Date
K232275	Invictus® Spinal Fixation System	NKB, KWP, KWQ, OUR, PML	September 27, 2023
K241519	Invictus® Small Stature Spinal Fixation System	NKB, KWP, KWQ	June 21, 2024

IV. DEVICE DESCRIPTION

The *Invictus® Bands System* is a sublaminar fixation and ligament augmentation system consisting of bands, sleeves, connectors, and set screws that mate with 4.5 – 5.0 mm and 5.5 – 6.0 mm diameter rods. The *Invictus® Bands System* sleeves, connectors, and set screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The bands are comprised of a polyethylene terephthalate (PET) braid with a stainless steel malleable tip

and needle (leads) at the ends of the bands. The stainless steel leads are detached after insertion and are not intended to be implanted. Implants are available in a variety of sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient.

The *Invictus® Bands System* connectors accept various rod diameters and are appropriate for use with any 4.5 – 5.0 mm and 5.5 – 6.0 mm diameter rod-based spinal fixation system cleared by FDA.

The bands are for single use and are provided terminally sterile via gamma irradiation. The sleeves, connectors, and set screws are for single use and are provided non-sterile to be steam sterilized by the end user. The system includes class I, reusable surgical instruments made of stainless steel and other materials and are provided non-sterile to be cleaned and steam sterilized by the end user.

V. INDICATIONS FOR USE

The *Invictus® Bands System* consists of temporary implants for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;
- Use with a posterior spinal instrumentation construct when ligament augmentation is needed.

The *Invictus® Bands System* may also be used in conjunction with other medical implants made of commercially pure titanium, titanium alloy, or cobalt chrome whenever "wiring" may help secure the attachment of other implants.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject *Invictus® Bands System* are substantially equivalent to the primary predicate *LigaPASS™ 2.0 Ligament Augmentation System* (K213659) and the additional predicates devices *Invictus® Spinal Fixation System* (K232275) and *Invictus® Small Stature Spinal Fixation System* (K241519).

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 Bands System*:

- ASTM F1798 Static Band Pull-Through
- ASTM F1798 Dynamic Band Pull-Through

The results demonstrate that the subject *Invictus® Bands 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.