January 13, 2026

Spinal Resources, Inc.
% Nathan Wright
Engineer & Regulatory Specialist
Applied Technical Services (Empirical Technologies)
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K252461
Trade/Device Name: Swedge™ Pedicle Screw Fixation System Bezier Rod
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: December 12, 2025
Received: December 12, 2025

Dear Nathan Wright:

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.

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 -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

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.	K252461

Please provide the device trade name(s).

Swedge™ Pedicle Screw Fixation System Bezier Rod

Please provide your Indications for Use below.

The Swedge™ Pedicle Screw Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudoarthrosis and failed previous fusion.

The Swedge™ Bezier rods may be used with compatible systems that use 4.75, 5.0, 5.5, and 6.0mm posterior rods made from either titanium alloy or cobalt chrome alloys. When connected to compatible systems, the Swedge™ Bezier rods are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e., scoliosis and/or kyphosis), spinal tumor, pseudoarthrosis, and failed previous fusion.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rod requirements.

The Swedge™ Pedicle Screw Fixation System is also intended for non-cervical pedicle screw fixation for the following indications: DDD (degenerative disc disease) severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: DDD (degenerative disc disease); trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252461 – 510(K) SUMMARY

Submitter's Name:	Spinal Resources, Inc.
Submitter's Address:	975 N. Federal Highway, Suite 250 Fort Lauderdale, Florida 33308
Submitter's Telephone:	904-540-9049
Contact Person:	Nathan Wright, MS, RAC Applied Technical Services (Empirical Technologies) 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	December 12, 2025
Trade or Proprietary Name:	Swedge™ Pedicle Screw Fixation System Bezier Rod
Device Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification & Regulation #:	Class II per 21 CFR §888.3070
Product Code:	NKB
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Swedge™ Pedicle Screw Fixation System is an implant device made from a titanium alloy (Ti-6Al-4VELI) and Cobalt Chrome. The subject device is to be implanted from the posterior approach. The screws are available as either solid or cannulated in diameters from 4.5mm – 8.5mm and in lengths from 25mm – 120 mm. Titanium Alloy and Cobalt Chromium rods are available in 4.75mm – 6.0mm diameters either straight or pre-curved in lengths from 25-600 mm. Transition (Bezier) rods are also included with a tapered diameter from 4.75mm –6.0 mm and lengths of 60mm – 600mm. The system also includes locking set screws, cross-links connectors, standard, reduction and Long polyaxial tulip heads along with the associated instrumentation to complete the procedure and implant construct.

The purpose of this 510(k) submission is to modify the indications for use to include use of the Bezier rods with compatible pedicle screws of other pedicle screw systems beyond the Swedge™ system.

INDICATIONS FOR USE

The Swedge™ Pedicle Screw Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudoarthrosis and failed previous fusion.

The Swedge™ Bezier rods may be used with compatible systems that use 4.75, 5.0, 5.5, and 6.0mm posterior rods made from either titanium alloy or cobalt chrome alloys. When connected to compatible systems, the Swedge™ Bezier rods are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e., scoliosis and/or kyphosis), spinal tumor, pseudoarthrosis, and failed previous fusion.

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TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have identical technological characteristics, and the modification in indicated use does not raise any new issues of safety and effectiveness as demonstrated through performance testing. The following characteristics are the same between the subject and predicates:

- Structure and Function
- Materials of manufacture
- Styles and Sizes
- Sterilization
- Biocompatibility

Primary Predicate Device

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	Product Code
K230482	Swedge™ Pedicle Screw Fixation System	Spinal Resources, Inc.	NKB

PERFORMANCE DATA

The Swedge™ Pedicle Screw Fixation System has been tested in the following test modes:

- Axial Grip per ASTM F1798
- Torsion Grip per ASTM F1798
- Dynamic Compression Bending per ASTM F1717

Testing was performed on a range of screw designs from different manufacturers to demonstrate compatibility with the Swedge™ Pedicle Screw Fixation System Bezier Rods with a range of screw designs.

The results of this non-clinical testing show that the strength and performance of the Swedge™ Pedicle Screw Fixation System Bezier Rods is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Swedge™ Pedicle Screw Fixation System is substantially equivalent to the predicate device.