March 23, 2023

Spinal Resources, Inc.
% Ms. Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K230482
Trade/Device Name: Swedge™ Pedicle Screw Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: February 22, 2023
Received: February 22, 2023

Dear Ms. Scifert:

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) 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

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)*
K230482

Device Name
Swedge™ Pedicle Screw Fixation System

Indications for Use *(Describe)*
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™ Pedicle Screw Fixation System is also intended for non-cervical pedicle screw fixation for the following indications: 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.

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.

510(k) Summary
Swedge™ Pedicle Screw Fixation System
Date Prepared: 22 February 2023

Company:
Spinal Resources Inc.
5975 N. Federal Highway
Suite 250
Fort Lauderdale, FL 33308
904-540-9049

Company Contact:
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Official Correspondent:
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Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Swedge™ Pedicle Screw Fixation System

Common Name: Thoracolumbosacral Pedicle Screw System

Classification: Class II

Regulation Number: 21 CFR 888.3070 (Thoracolumbosacral pedicle screw system)

Panel: Orthopedic

Product Code: NKB

Device Description:
The Swedge™ Pedicle Screw Fixation System is an implant device made from a titanium alloy (Ti-6Al-4V-ELI) 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 Chrome rods are available in 4.75mm – 6.0mm diameters either straight or pre-curved in lengths from 25-600 mm. Transition rods are also included with a tapered diameter from 4.75mm –5.5mm 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.

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™ Pedicle Screw Fixation System is also intended for non-cervical pedicle screw fixation for the following indications: 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.

Substantial Equivalence:
The subject Swedge™ Pedicle Screw Fixation System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Spinal Resources, Inc., Swedge™ Pedicle Screw Fixation System (K170045)

Secondary Predicate:

- Stryker Spine, XIA 4.5 Spinal System (K121342)

There are insignificant differences between the subject Swedge™ Pedicle Screw Fixation System and the predicates. The Indications for Use and Materials are identical to those for the previously cleared Swedge™ Pedicle Screw System (K170045). The geometry for predicate devices are all inclusive of the subject device. Testing shows that the subject Swedge™ Pedicle Screw Fixation System performs equivalent to the predicate Swedge™ Pedicle Screw Fixation System (K170045). Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
The following mechanical testing has been performed on the subject Swedge™ Pedicle Screw Fixation System: per ASTM F1717 - Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model - static compression bending, static torsion, and dynamic compression bending.

Conclusion:

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.