October 28, 2024

Spinal Alignment Solutions, Inc.
% Christine Scifert
Partner
MRC Global, LLC
9085 East Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K242350
Trade/Device Name: Spinal Alignment Solutions Pelvic Incidence (PI) Rod System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 30, 2024
Received: August 8, 2024

Dear Christine 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 (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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.10.28 14:23:43 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K242350

Device Name
Spinal Alignment Solutions Pelvic Incidence (PI) Rod System

Indications for Use *(Describe)*
The Spinal Alignment Solutions Pelvic Incidence (PI) Rod System is indicated for the use with Medtronic CD Horizon™ SOLERA™ Spinal System which is intended for posterior, lumbar and sacral fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD - 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, or lordosis), tumor, pseudarthrosis, and/or 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Spinal Alignment Solutions Pelvic Incidence (PI) Rod System

24 October 2024

Company: Spinal Alignment Solutions, Inc.
1745 Main Rd
Tiverton, RI 02878
(260) 797-1345

Company Contact: Dr. Bassel Diebo
President and CEO
(260) 797-1345
Dr.basseldiebo@gmail.com

Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Spinal Alignment Solutions Pelvic Incidence (PI) Rod 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 Spinal Alignment Solutions Pelvic Incidence (PI) Rod System consists of pre-bent spinal rods compatible for use with the Medtronic CD Horizon™ SOLERA™ Spinal System. The SAS PI Rod System is manufactured from either titanium alloy or cobalt chrome.

The CD Horizon™ Spinal System consists of a variety of shapes and size of rods, screws, CROSSLINK® Plates, and connecting components which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Indications for Use:

The Spinal Alignment Solutions Pelvic Incidence (PI) Rod System is indicated for the use with Medtronic CD Horizon™ SOLERA™ spinal system which is intended for posterior, lumbar and sacral

fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD - 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, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Substantial Equivalence:
The subject Spinal Alignment Solutions Pelvic Incidence (PI) Rod System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Medtronic CD Horizon™ Spinal System – K113174

Additional Predicates:

- Medtronic CD Horizon™ Spinal System - K202771; K221646

The Spinal Alignment Solutions Pelvic Incidence (PI) Rod System indications for use are encompassed by the indications for use for the predicate Medtronic devices. The materials, manufacturing, sterilization, and MR compatiblity of the subject device is identical to that of the predicate Medtronic CD Horizon™ Spinal System (K221646). The design of the subject device is similar to that of that of the Medtronic CD Horizon™ rods and UNiD Rods. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
When used with the Medtronic CD Horizon™ SOLERA™ Spinal System the subject SAS PI Rods have the same fundamental scientific technology, indications for use, intended use, materials, manufacturing processes, and levels of attachment as the predicate CD Horizon™ SOLERA™ Spinal System devices. The subject device does not introduce a new worst case condition and therefore, no additional mechanical testing was performed.

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.