



September 30, 2026

Spinal Alignment Solutions, Inc.
% Christine Scifert
Partner
MRC Global, LLC
9160 Hwy. 64 Suite 12
Lakeland, Tennessee 38002

Re: K263172

Trade/Device Name: SAS MIS Pelvic Incidence Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: September 10, 2026
Received: September 10, 2026

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.

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).

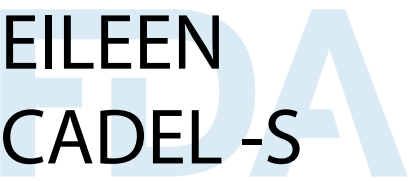
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,


**EILEEN
CADEL-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.

K263172

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Please provide the device trade name(s).

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SAS MIS Pelvic Incidence Rods

Please provide your Indications for Use below.

?

The Spinal Alignment Solutions MIS PI-Rod 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.

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary
SAS MIS Pelvic Incidence Rods
24 September 2026

Company: Spinal Alignment Solutions, Inc.
8044 Market Street STE A
Wilmington, NC 28411
(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: SAS MIS Pelvic Incidence Rods

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 SAS MIS Pelvic-Incidence (PI) Rods are pre-bent spinal rods compatible for use with the Medtronic CD Horizon™ SOLERA™ Spinal System. The SAS MIS 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 MIS PI-Rod 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 SAS MIS PI-Rods are substantially equivalent to the following predicate device:

Primary Predicate:

- Spinal Alignment Solutions Pelvic Incidence (PI) Rod System – K242350

The SAS MIS PI-Rods indications for use are identical to the indications for use for the predicate SAS PI-Rod device. The materials, manufacturing, and sterilization of the subject device is identical to that of the predicate SAS PI-Rod System (K242350). The design of the subject device is identical to SAS PI-Rods with the two (2) differences being:

- inclusion of a longer rod length, 200mm (subject) vs. 175mm (predicate)
- a rod-end connection feature at each end of the subject rod that engages the SAS MIS Rod Inserter for controlled single-instrument rod delivery

These changes to the subject device do not raise new questions about safety and effectiveness.

Performance Testing:

The key design characteristics of the subject SAS MIS PI-Rods are equivalent to those of the predicate SAS PI-Rods when each are used with the CD Horizon™ SOLERA™ Spinal System. The subject device does not introduce a new worst case condition and therefore, no additional mechanical testing was performed. The subject device is expected to perform equivalently to the predicate rods.

Conclusion:

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