April 29, 2026

ZheJiang Decans Medical Devices Co., Ltd.
% Xiaoqing Xue
Registration Engineer
Sinow Medical AS
Vestre Fantoftåsen 44, 5072
Bergen,
Norway

Re: K252542
Trade/Device Name: LEO Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: April 1, 2026
Received: April 1, 2026

Dear Xiaoqing Xue:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252542

Device Name
LEO Spinal System

Indications for Use *(Describe)*
The LEO Spinal System is intended for use in the noncervical spine. When used as a posterior, noncervical pedicle and non-pedicle fixation system, the LEO Spinal System is intended as an adjunct to fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: 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, Deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), Tumor, Pseudoarthrosis, 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

Preparation Date:	April 24, 2026	
Submitter	ZheJiang Decans Medical Devices Co., Ltd. No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031,P.R. China	
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Designated Submission Correspondent	Company: Sinow Medical AS Address: Vestre Fantoftåsen 44, 5072, Bergen, Norway Contact Person: Xiaoqing Xue Telephone: +86 15161196032 Email: xue@bergemed.com	
Subject Device	Trade name	LEO Spinal System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3070
	Classification Name	Thoracolumbosacral Pedicle Screw System
	Product Codes	NKB, KWP
	Common name for product codes	Thoracolumbosacral pedicle screw system
Primary Predicate Device	Manufacturer	Stryker Spine
	Trade name	XIA® 3 Spinal System
	510(K) number	K113666
	Regulatory Class	II/III
	Regulation Number	888.3070
	Classification Name	Thoracolumbosacral Pedicle Screw System
	Product Codes	NKB, OSH, KWP, MNH, MNI
Additional Predicate Device	Manufacturer	Medtronic Sofamor Danek, USA Inc.
	Trade name	CD HORIZON Legacy Spinal System
	510(K) number	K223494
	Regulatory Class	II
	Regulation Number	888.3070
	Classification Name	Thoracolumbosacral Pedicle Screw System
	Product Codes	NKB, KWP, KWQ, HBE, OLO

Indications for use	The LEO Spinal System is intended for use in the noncervical spine. When used as a posterior, noncervical pedicle and non-pedicle fixation system, the LEO Spinal System is intended as an adjunct to fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: 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, Deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), Tumor, Pseudoarthrosis, Failed previous fusion.
Device Description	The LEO Spinal System is a medical device system for surgical fixation of the spine. The system includes Ø5.5mm, Ø6.0mm and Ø6.35 type rod diameters and consists of a variety of shapes and sizes of rods, pedicle screws (fixed angle screws, fixed angle reduction screws, multi-axial screws and multi-axial reduction screws), crosslinks, set screw, hooks, and connectors. All components are made from titanium alloy (Ti6Al4V) per ISO 5832-3. LEO Spinal System, which can be rigidly locked into a variety of configurations, are applicable for each construct being tailor-made for the individual case. The proposed implants are provided non sterile and for single use. It is required to be cleaned and sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. Validated manual cleaning and steam sterilization instructions are provided for the end user before implantation. The recommended sterilization method was validated as per ISO 17665-1. The surgical instruments may be reprocessed and re-used. This system also contains Class I manual surgical instruments that are considered exempt from premarket notification.
Materials	Titanium alloy (Ti6Al4V) per ISO 5832-3
Summary of indications for use and technological characteristics	The LEO Spinal System is substantially equivalent to the predicate devices when evaluating indications for use and technological characteristics (e.g., intended use, materials, design, and function).

Non-clinical testing	Performance bench testing The following testing items were conducted for the subject device: • Static Axial Compression Bending Testing per ASTM F1717-21 •Dynamic Compression Bending testing per ASTM F1717-21 • Static Torsional Testing per ASTM F1717-21 Cleaning and Sterilization The implant devices are provided non-sterile. Validated manual cleaning and steam sterilization instructions are provided for the end user before implantation. The recommended sterilization method was validated as per ISO 17665-1. Biocompatibility test The following biocompatibility tests were performed per ISO10993-1, and the test results demonstrate that the device meets biological safety requirements. • In vitro cytotoxicity Test per ISO 10993-5 • Skin sensitization Test per ISO 10993-10 • Intracutaneous Reactivity Test per ISO 10993-23 • Pyrogen Test per ISO 10993-11 • Chemical Characterization per ISO 10993-18 • Toxicological risk assessment of extractable chemicals per ISO 10993-17
Performance - Animal	No animal study data is submitted in this 510(k).
Performance - Clinical	No clinical study data is submitted in this 510(k).
Conclusion	The non-clinical data demonstrates the LEO Spinal System is substantially equivalent to the predicate device.