Ingenium Spine
% Christine Scifert
Partner
MRC Global, LLC
9085 East Mineral Circle
Suite 110
Centennial, Colorado 80112

June 4, 2024

Re: K241258
Trade/Device Name: Ingenix Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: May 3, 2024
Received: May 6, 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.

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: 2024.06.04 14:29:00 -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

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)*
K241258

Device Name
Ingenix Spinal System

Indications for Use *(Describe)*
The Ingenix™ Spinal 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, scoliosis, kyphosis, spinal tumor, severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra with autogenous bone graft, and failed previous fusion (pseudarthrosis).

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.

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510(k) Summary

Ingenix Spinal System
3 June 2024

Company: Ingenium Spine
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Tempe, AZ 85281
Phone: (602) 281-7965

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Company Contact: David Brumfield
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Ingenium Spine
901-277-7381
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Trade Name: Ingenix Spinal System

Common Name: Thoracolumbosacral pedicle screw system

Classification: Class II

Regulation: 21 CFR 888.3070 (Thoracolumbosacral pedicle screw system)

Panel: Orthopedic

Product Code: NKB

Device Description:

The Ingenix™ Spinal System (originally cleared as "Arisstos Spinal System") is an internal fixation device for spinal surgery consisting of rods, screws, and connectors available in various sizes to accommodate patient anatomy. A series of manual instruments intended to assist in the insertion and placement of the implants, such as taps, drivers, and rod benders, is provided in separate instrument trays.

The subject rods, screws, and connectors are manufactured of Ti-6Al-4V titanium alloy per ASTM F136. Additionally, 5.5mm and 6.0mm cobalt chrome rods are also available, conforming to ASTM F1537. All instruments are manufactured from stainless steel, aluminum, and select polymers.

The subject submission seeks to gain clearance for the following:

- Minor modifications made to screws
- Size expansion for the polyaxial deformity screws
- Sterile packaging of a kit configuration

Indications for Use:

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Substantial Equivalence:

The subject Ingenix™ Spinal System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Ingenium Arisstos™ Spinal System – K173126

The subject components are identical in indications, similar in sizing and geometry, technological characteristics, and identical in materials to the predicate. The only substantial difference between the subject device and predicate device is that the subject device is provided sterile via Ethylene Oxide sterilization and the predicate device is provided non-sterile.

Performance Testing:

The following bench performance testing has been conducted on the subject screws per ASTM F1798-13: Static axial grip, Flexion-extension moment, and Flexion-extension fatigue. All testing showed that the subject devices performed substantially equivalent to predicate devices. Additionally, cleaning, sterilization, and packaging validations have been performed with the subject devices meeting or exceeding all acceptance criteria.

Conclusion:

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