December 5, 2017

Ingenium Spine
% Ms. Christine Scifert
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

Re: K173126
Trade/Device Name: Arisstos™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: September 27, 2017
Received: September 29, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173126

Device Name
Arisstos™ Spinal System

Indications for Use *(Describe)*

The Arisstos™ 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 the thoracic, lumbar and sacral spine: degenerative spondylolisthesis, with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The Arisstos™ Spinal System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients undergoing fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid 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 - Traditional
Arisstos™ Spinal System

November 20, 2017

Company: Ingenium Spine
3145 E. Chandler Blvd. #110
Phoenix, AZ 85048
U.S.A.
Tel: 888-684-7861
FAX: 928-212-3041

Primary Contact: Christine Scifert
Phone: 901-831-8053

Company Contact: David Brumfield
Ingenium Spine

Trade Name: Arisstos™ Spinal System

Common Name: Thoracolumbosacral Pedicle Screw System
Appliance, Fixation, Spinal Interlaminal;

Classification: Class II

Regulation Number: 21 CFR 888.3070 (Thoracolumbosacral Pedicle Screw System)
21 CFR 888.3050 (Spinal interlaminal fixation orthosis)

Panel: 87- Orthopedic

Product Codes: NKB, KWP

Predicate Devices:

Primary Predicate Device:

- Showa Ika Kohgyo Co., LTD: MYKRES® Spinal System– K051704 (Cleared 07/03/2006)

Secondary Predicate Device:

- Medtronic Sofamor Danek: CD® HORIZON Spinal System – K043488 (Cleared 03/21/2005) & K163301 (Cleared 12/20/2016)

Device Description:
The Arisstos™ Spinal System is an internal fixation device for spinal surgery consisting of rods, screws, hooks and connectors available in various lengths, diameters, and configurations to enable close conformance to patient anatomy. A series of manual instruments intended to assist in the insertion and placement of the implants is provided in separate trays.

Indications for Use:
The Arisstos™ 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 the thoracic, lumbar and sacral spine: degenerative spondylolisthesis, with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The Arisstos™ Spinal System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients undergoing fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

Substantial Equivalence:
The subject pedicle screw spinal fixation system is substantially equivalent to the following predicate devices with respect to indications for use, design, dimension, and materials.

Primary Predicate Device:
- Showa Ika Kohgyo Co., LTD: MYKRES® Spinal System– K051704 (Cleared 07/03/2006)

Secondary Predicate Device:
- Medtronic Sofamor Danek USA, Inc: CD HORIZON® Spinal System – K043488 (Cleared 03/21/2005) & K163301 (Cleared 12/20/2016)

The minor differences between the Arisstos™ and the predicate devices raise no new questions of safety and effectiveness.

Performance Testing:
Mechanical testing, including static compression bending, dynamic compression bending, and static torsion was performed per ASTM F1717 to establish that the mechanical properties of the subject devices are equivalent to the predicate devices.