December 22, 2022

SpineCraft, LLC
Ami Akallal-Asaad
Vice President of Regulatory Affairs & Quality Assurance
777 Oakmont Lane, Suite 200
Westmont, Illinois 60559

Re: K223273
Trade/Device Name: ASTRA Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: October 19, 2022
Received: October 24, 2022

Dear Ami Akallal-Asaad:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Colin O'neill -S

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)*

K223273

Device Name
ASTRA Spine System

Indications for Use *(Describe)*

The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The ASTRA Spine System is indicated for non-cervical (T1-S2/Ilium) pedicle fixation and non-pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture and/or dislocation); spinal stenosis; deformities (scoliosis, lordosis and/or kyphosis); spinal tumor; and failed previous fusion (pseudo-arthrosis).

When used in a percutaneous, posterior approach with AVANT Spine MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (DDD - defined as discogenic back pain 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, and/or lordosis), tumor, pseudo-arthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ASTRA Spine System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the ASTRA Spine System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The ASTRA fenestrated screw when used with other components of the ASTRA Spine System is indicated to provide the surgeon with an open or minimally invasive approach for posterior spinal surgery. The ASTRA fenestrated screw is intended to be used with saline or radiopaque dye.

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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5*10*(k) Summary
for the ASTRA Spine System
In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the ASTRA Spine System

Date Prepared: November 15, 2022

1. Submitter:

SpineCraft, LLC
777 Oakmont Lane
Westmont, IL 60559 USA
Tel: 1 630-920-7300
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Contact Person:

Ami Akallal-Asaad
VP, Regulatory Affairs & QA
SpineCraft, LLC
a.asaad@spinecraft.com

2.

Trade name:	ASTRA Spine System
Common Name:	Pedicle screw system
Classification Name:	Thoracolumbosacral pedicle screw system per NKB 888.3070 Spinal interlaminal fixation orthosis per KWP 888.3050 Spinal intervertebral body fixation orthosis per KWQ 888.3060 Class II

2. Primary predicate or legally marketed device which is substantially equivalent:

- Firebird Spinal Fixation Systems, Phoenix MIS Fixation System and JANUS Fenestrated Screws (K180179) / Orthofix Inc.

3. Additional predicate devices:

- ASTRA Spine System (K150417 / K211323) / SpineCraft.
- REVLOK™ Fenestrated Screw System (K110280) / Globus Medical Inc

4. Description of the device:

The ASTRA Spine System consists of Ø 5.5mm, Ø 6.0mm and Ø 6.2mm longitudinal, lordosed, contoured and revision rods, pedicle screws (monoaxial, polyaxial, and uniplanar), cannulated pedicle screws (standard and reduction monoaxial, standard, reduction & extended tab polyaxial and standard & reduction uniplanar), fenestrated screws (standard, reduction & extended tab polyaxial and standard & reduction uniplanar), hooks (standard & reduction), lateral iliac connectors, rod-to-rod connectors and transverse (cross) connectors. Most of the components are available in a variety of sizes to more closely match the patient's anatomy.

The safety and effectiveness of the ASTRA fenestrated screw has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g.,osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

Materials:
Titanium alloy per ASTM F136 and CoCr alloy per ASTM F1537

5. Substantial equivalence claimed to predicate devices

ASTRA Spine System (Additions) is substantially equivalent to Firebird Spinal Fixation Systems, Phoenix MIS Fixation System and JANUS Fenestrated Screws (K180179), ASTRA Spine System (K150417 / K211323), and the REVLOK™ Fenestrated Screw System (K110280), in terms of intended use, design, materials used, mechanical safety and/or performances.

6. Indications for Use:

The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The ASTRA Spine System is indicated for non-cervical (T1-S2/Ilium) pedicle fixation and non-pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture and/or dislocation); spinal stenosis; deformities (scoliosis, lordosis and/or kyphosis); spinal tumor; and failed previous fusion (pseudo-arthrosis).

When used in a percutaneous, posterior approach with AVANT Spine MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (DDD - defined as discogenic back pain 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, and/or lordosis), tumor, pseudo-arthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ASTRA Spine System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the ASTRA Spine System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The ASTRA fenestrated screw when used with other components of the ASTRA Spine System is indicated to provide the surgeon with an open or minimally invasive approach for posterior spinal surgery. The ASTRA fenestrated screw is intended to be used with saline or radiopaque dye.

7. Non-clinical Test Summary:

The following tests were conducted:

- ASTM F1717, “Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model”. Testing included Static Compression Bending Tests, Static Torsion Tests and Dynamic Compression Bending Tests.
- ASTM F1798 “Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies used in Spinal Arthrodesis Implants”. Testing included Axial Gripping and Torsional Gripping.

The results of this testing were compared to predicate systems, with the results being equal to or higher than the predicate systems.

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

Based on the supporting evidence provided, we believe that the subject ASTRA Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.