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

Re: K181350
Trade/Device Name: ASTRA-OCT Spine System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: May 18, 2018
Received: May 22, 2018

Dear Ms. 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. 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 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,

Colin O'neill -S
for MNM

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)*
K181350

Device Name

ASTRA-OCT Spine System

Indications for Use *(Describe)*

The ASTRA-OCT Spine System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3):

- Traumatic spinal fractures and/or Traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g. pseudoarthrosis);
- Tumors involving the cervical/thoracic spine; and
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The ASTRA-OCT Spine System implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the ASTRA-OCT Spine System rods may be connected to other occipital cervical thoracic or thoracolumbar stabilization rod systems ranging in diameter from 3.5mm to 6.35mm, including the ASTRA or APEX Spine Systems, using corresponding connectors.

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-OCT 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-OCT Spine System.

Date Prepared: July 6, 2018

1. **Submitter:**

SpineCraft, LLC
777 Oakmont Lane
Westmont, IL 60559 USA
Tel: 1 630-920-7300.
Fax: 1 630-920-7310

Contact Person:

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

2. **Trade name:** **ASTRA-OCT Spine System**

Classification Name: Orthosis, cervical pedicle screw spinal fixation NKG
Unclassified, Pre-Amendment

Spinal interlaminal fixation orthosis per KWP 888.3050
Class II

3. **Primary predicate or legally marketed device which is substantially equivalent:**
   - **MOUNTAINEER OCT Spinal System** (Depuy Spine) cleared in 510(k): K080828 / K110353 / K151885

4. **Additional predicate devices:**
   - **VERTEX Reconstruction System** (K090714 / K091365 / K093434 / K110522 / K123656 / K143471) Medtronic
   - **SYNAPSE System** (K090549 / K133698 / K141897 / K142838) Synthes Spine
   - **Summit OCT** (K013222 / K022190/ K030103 / K041203 / K151885) Depuy Spine
   - **ELLIPSE and PROTEX CT** Occipito-Cervico-Thoracic Spinal Systems (K150552) Globus Medical
   - **Kestrel Posterior Cervical Spine System** (K132122) SPINE360

5. **Reference predicate devices**
   - **Rogozinski** (K954696) Smith & Nephew Spine
   - **APEX-DL Spine System** (K143683) SpineCraft

6. **Description of the device:**

The **ASTRA-OCT Spine System** consists of a series of polyaxial screws, occipital screws, occipital plates, hooks, rods, lateral connectors, rod-to-rod connectors, set screws, and cross connectors.

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

7. **Substantial equivalence claimed to predicate devices**

ASTRA Spine System is substantially equivalent to the **MOUNTAINEER OCT Spinal System** (K042508 / K080828 / K103100 / K110353 / K132332 / K151885) and **VERTEX Reconstruction**

System (K090714 / K091365 / K093434 / K110522 / K123656 / K143628) in terms of intended use, design, materials used, mechanical safety and/or performances.

8. Indications for Use:

The ASTRA-OCT Spine System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3):

- Traumatic spinal fractures and/or Traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g. pseudoarthrosis);
- Tumors involving the cervical/thoracic spine; and Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

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9. Summary of the technological characteristics compared to predicate

Intended Use
The **ASTRA-OCT Spine System** and all the predicates have similar intended uses.

Materials
The **ASTRA-OCT Spine System** is fabricated from the same material as the predicate devices.

Design Features/Functions
The **ASTRA-OCT Spine System** and the cited predicate devices share similar basic design features and functions.

Dimensions
The **ASTRA-OCT Spine System** is dimensionally similar to the cited predicate devices.

Sterilization
The **ASTRA-OCT Spine System** is provided non-sterile and the cited predicate devices are non-sterile for single use only.

Performance Specification
Mechanical testing confirmed the **ASTRA-OCT Spine System** demonstrated equivalent performance to the cited predicate device under the same test conditions.

10. 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 F2706, “Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model”. Testing included Static Compression

Bending Tests, Static Tension Bending Test, Static Torsion Tests, Dynamic Compression Bending Tests and Dynamic Torsion 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, Torsional Gripping, Static A-P, Static Flexion-Extension and Dynamic Flexion-Extension.

The results of this testing were compared to predicate systems, with the **ASTRA-OCT Spine System** results being equivalent to the predicate systems.

11. Clinical Test Summary

No clinical studies were performed

12. Conclusion Nonclinical and Clinical

Published literature and performance testing demonstrate that the ASTRA-OCT Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.