July 20, 2023

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

Re: K223301
Trade/Device Name: ASTRA & AVANT Navigation Instruments System and ASTRA-OCT Navigation Instruments System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 12, 2023
Received: June 14, 2023

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

Device Name
ASTRA and AVANT Navigation Instruments System
And
ASTRA-OCT Navigation Instruments System

Indications for Use *(Describe)*

ASTRA and AVANT Navigated Reusable Instruments are indicated for preparation and placement of SpineCraft ASTRA Spine system pedicle screws during thoracolumbar sacroiliac spinal surgery to assist surgeon in precisely locating anatomical structures in either open, minimally invasive procedures, or percutaneous, procedures.
ASTRA and AVANT Navigated Reusable Instruments are specifically designed for use with Medtronic StealthStation® System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Use of the ASTRA and AVANT Navigated Reusable Instruments is limited to use only with ASTRA Spine System implants.

ASTRA-OCT Navigated Reusable instruments are indicated for preparation and placement of SpineCraft ASTRA-OCT Spine system screws during cervico-thoracic spinal surgery to assist surgeon in precisely locating anatomical structures in open procedures.
ASTRA-OCT Navigated Reusable Instruments are specifically designed for use with Medtronic StealthStation® SystemS8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Use of the ASTRA-OCT Navigated Reusable Instruments is limited to use only with ASTRA-OCT Spine System implants.

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
for the ASTRA, AVANT and ASTRA-OCT Navigation Instruments Systems

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
The following 510(k) Summary is submitted for the ASTRA, AVANT and ASTRA-OCT Navigation Instruments Systems

Date Prepared: July 20, 2023

1. Submitter:

SpineCraft, LLC
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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 & AVANT Navigation Instruments System
ASTRA-OCT Navigation Instruments System

Common Name: Computer Assisted Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Device Class Class II
Product Code: OLO

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

ASTRA & AVANT Navigation

- **Navigated CD Horizon Solera** (Medtronic) cleared in 510(k): K140454

ASTRA-OCT Navigation

- **Navigated Infinity Instruments** (Medtronic) cleared in 510(k): K173338

4. Reference devices:

- **Navigated Manual Reusable Instruments** (Medtronic) cleared in 510(k): K153442
- **ASTRA Spine System** (SpineCraft) cleared in 510(k): K150417 and K211323
- **ASTRA-OCT Spine System** (SpineCraft) cleared in 510(k): K181350

5. Description of the device:

The ASTRA, AVANT and ASTRA-OCT Navigation instruments are non-sterile, reusable surgical instruments designed for compatibility with the Medtronic NavLock Trackers and to ultimately provide seamless interaction with the Medtronic StealthStation® System. The ASTRA and AVANT Navigation instruments are for use with ASTRA Spine System pedicle screws and the ASTRA-OCT Navigation instruments are for use with ASTRA-OCT Spine System pedicle screws. The instruments are manufactured from medical grade stainless steel. The ASTRA, AVANT & ASTRA-OCT navigation instruments are available in same or similar diameters and lengths as the corresponding predicate Medtronic navigated instruments. This includes awls, probes, drill bits, taps and screwdrivers.

6. Materials:

Medical grade stainless steel per ASTM F899

7. Substantial equivalence claimed to predicate devices

ASTRA & AVANT Navigation Instruments System is substantially equivalent to the **Navigated CD Horizon Solera system** (K140454) and **Navigated Manual Reusable Instruments** (K153442) in terms of intended use, design, materials used, mechanical safety and/or performances.

ASTRA-OCT Navigation Instruments System is substantially equivalent to the **Navigated Infinity Instruments system** (K173338) in terms of intended use, design, materials used, mechanical safety and/or performances.

8. Indications for Use:

ASTRA and AVANT Navigated Reusable Instruments are indicated for preparation and placement of SpineCraft ASTRA Spine system pedicle screws during thoracolumbar sacroiliac spinal surgery to assist surgeon in precisely locating anatomical structures in either open, minimally invasive procedures, or percutaneous, procedures.
ASTRA and AVANT Navigated Reusable Instruments are specifically designed for use with Medtronic StealthStation® System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Use of the ASTRA and AVANT Navigated Reusable Instruments is limited to use only with ASTRA Spine System implants.

ASTRA-OCT Navigated Reusable instruments are indicated for preparation and placement of SpineCraft ASTRA-OCT Spine system screws during cervico-thoracic spinal surgery to assist surgeon in precisely locating anatomical structures in open procedures.
ASTRA-OCT Navigated Reusable Instruments are specifically designed for use with Medtronic StealthStation® System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Use of the ASTRA-OCT Navigated Reusable Instruments is limited to use only with ASTRA-OCT Spine System implants.

9. Summary of the technological characteristics compared to predicate

Intended Use

The **ASTRA, AVANT and ASTRA-OCT Navigation instruments Systems** and all the corresponding predicates have similar intended uses.

Materials

The **ASTRA, AVANT and ASTRA-OCT Navigation instruments System** are fabricated from the same material as the corresponding predicate devices.

Design Features/Functions

The **ASTRA, AVANT and ASTRA-OCT Navigation instruments Systems** and the cited corresponding predicate devices share similar basic design features and functions.

Dimensions

The **ASTRA, AVANT and ASTRA-OCT Navigation instruments Systems** are dimensionally similar to the cited corresponding predicate devices.

Sterilization

The **ASTRA, AVANT and ASTRA-OCT Navigation instruments Systems** are reusable provided non-sterile and the cited corresponding predicate devices are reusable and non-sterile.

Performance Specification

Performance testing conducted on the **ASTRA, AVANT and ASTRA-OCT Navigation instruments Systems** demonstrated that they perform as designed, are suitable for their intended use and are substantially equivalent to the cited corresponding predicate devices under the same test conditions.

10. Non-clinical Test Summary:

A detailed dimensional analysis and one-to-one comparison has been conducted for subject and predicate device to support the substantial equivalence.

Additionally, the **ASTRA, AVANT and ASTRA-OCT Navigation instruments Systems** have been tested per ASTM F2554-18 “Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems”.

- Single point measurement accuracy per ASTM F2554-18
- Instrument axis rotation measurement accuracy per ASTM F2554-18
- Instrument angular position perpendicular to the system camera measurement accuracy per ASTM F2554-18
- Instrument angular position parallel to the system camera measurement accuracy per ASTM F2554-18
- Distance between points measurement accuracy per ASTM F2554-18

The results of this non-clinical testing together with the dimensional analysis and comparison show that performance of the **ASTRA, AVANT and ASTRA-OCT Navigation Instruments Systems** is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices

11. Clinical Test Summary

No clinical studies were performed

12. Conclusion Nonclinical and Clinical

The overall technology characteristics and performance data lead to the conclusion that the **ASTRA, AVANT and ASTRA-OCT Navigation Instruments Systems** are substantially equivalent to the cited corresponding predicate devices in terms of indications for use, design, material, performance and function.