December 9, 2022

SeaSpine Orthopedics Corporation
% Elena Marenny
Regulatory Specialist
7D Surgical ULC
60 Scarsdale Road, Unit 118
Toronto, ON M3B 2R7
Canada

Re: K222753
Trade/Device Name: SeaSpine 7D Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 7, 2022
Received: September 12, 2022

Dear Elena Marenny:

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,

Jesse Muir -S

For: 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)*
K222753

Device Name
SeaSpine 7D Navigation Instruments

Indications for Use *(Describe)*
The SeaSpine 7D Navigation Instruments are intended to be used during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SeaSpine 7D Navigation Instruments are specifically designed for use with the 7D Surgical System, 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 can be identified.

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 of Safety and Effectiveness

THE SEASPINE 7D NAVIGATION INSTRUMENTS

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS SUBMITTED IN ACCORDANCE WITH 21CFR §807.92.

1. **Submitter's name, address, telephone number, contact person.**

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Carlsbad, CA 92008
Contact person: Jesse Albright
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Date prepared: December 09, 2022

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/usual name: Stereotactic Instrument
Proprietary name: SeaSpine 7D Navigation Instruments

These devices are classified as follows:

Classification Name	**21 CFR Section**	**Product Code**
Stereotaxic instrument	21 CFR §882.4560	OLO

3. **Substantially Equivalent Devices**

SeaSpine Orthopedics Corporation believes the SeaSpine Navigation Adapter is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
7D Surgical System- Universal Tracking Clamp (Primary)	K192140
Envision 3D™: Image Guidance System (7D Surgical System was initially named "Envision 3D ")	K162375

The indications for use of the subject device are equivalent to the predicate device K192140 and K162375. Furthermore, the technological characteristics of the SeaSpine Navigation Adapter are substantially equivalent. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the subject is substantially equivalent to the predicate device.

4. Indications for Use

The SeaSpine 7D Navigation Instruments are intended to be used during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SeaSpine 7D Navigation Instruments are specifically designed for use with the 7D Surgical System, 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 can be identified.

5. Device Description and Technical Comparison to Predicate Devices

The SeaSpine 7D Navigation Instruments are used during the preparation and placement of SeaSpine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SeaSpine 7D Navigation Instruments are wireless optically tracked and specifically designed for use with the 7D Surgical system.

The SeaSpine 7D Navigation Instruments utilize commercially available passive reflective marker spheres to determine the position and orientation of instruments. Each tracked Instruments requires a unique marker position configuration to enable the tracking system to distinguish the tools from one to the other. Position and orientation data of tracked Spinal Instruments are linked to the preoperative scan data using the 7D Surgical System workstation.

I. SeaSpine Navigation Adapter (K192140)

The SeaSpine Navigation Adapter designed to connect to a 7D Surgical Universal Array (1 or 2) allows for rotation and continuous visualization of compatible SeaSpine Insert (SeaSpine Mariner Nav Insert) in the navigated 7D Surgical System. As with predicate Universal Tracking Clamp 510(K) 192140 device, calibration of the 7D Surgical Integration Tools is required for the surgeon to proceed with he intended workflow using the 7D Surgical System.

II. SeaSpine Reference Clamp (K162375)

The SeaSpine Reference Clamp (Radiolucent) is designed to be used when rigid fixation to the spinous process is required. As with predicate 7D Surgical Reference Clamp K162375, the SeaSpine Reference Clamp attaches rigidly to the spinous process in the region where

the user plans to perform surgery. Once fixated, the user attaches the 7D Surgical Flex Array which holds the spherical markers which are tracked by the 7D Surgical System.

III. SeaSpine Pedicle Probe (K162375)

The SeaSpine Pedicle Probe is designed to extend the initial hole through the cancellous (soft) bone of the vertebra. As with predicate 7D Surgical Pedicle Probe K162375, the SeaSpine Pedicle probe Tracked Navigation Tool is used by the surgeon to perform image-guided surgery via 7D Surgical System integration, guiding the pedicle screws length selection and insertion into the vertebra.

6. Safety Considerations

The SeaSpine 7D Navigation Instruments add compatibility to the 7D System to include navigation and tracking of the SeaSpine compatible insert and tools did not impact conformity to regulatory compliance standards. Mechanical Design, and User Instructions risk control measures have been implemented to ensure all new risks associated with use of the SeaSpine 7D Navigation Instruments have been adequately controlled.

7. Technological Characteristics

The literature research and the comparison to the predicate devices show that the device makes use of equivalent technological characteristics and functionality and is intended for equivalent surgical procedures as compared to the predicate devices.

8. Nonclinical Performance Data

Verification and Validation activities have been conducted to provide assurance that the device meets the performance requirements under the indications for use conditions.

The following tests were performed to ensure the safety and effectiveness of the SeaSpine 7D Navigation Instruments:

- Non-Clinical System, Software, and Instrumentation Verification and Validation
- Non-Clinical Performance Surgical Simulations Conducted on Phantom Models
- Compliance Conformity Assessments
    - ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

Device performance tests were performed to verify the absolute accuracy and repeatability of the accuracy of the device, and the navigation accuracy according to ASTM F2554-10. In addition, Target Registration Error (TRE) and Angular Trajectory Error (ATE) has been used to evaluate the clinical accuracy of the system on phantom models in a clinical simulated environment. TRE and ATE evaluates the error discrepancy between the position of the SeaSpine Navigation Adapter, Reference Clamp, and Pedicle Probe reported by the image guided surgery system and the ground truth position measured physically or otherwise.

The following ***Table 1*** contains a summary of verification and validation performed on the 7D Surgical System:

Verification and Validation	Description	Conclusion
System Verification	Scope of the test is to verify the design requirement specifications of the SeaSpine Navigation Adapter, Reference Clamp, Pedicle Probe compatibility with the 7D Surgical System under test case protocols.	Verification successful, all design requirements have been fulfilled.
System Validation	Scope of the test is to validate the Indications for Use and Customer Requirements of the SeaSpine Navigation Adapter, Reference Clamp, Pedicle Probe compatibility with the 7D Surgical System under simulated use case situations.	Validation successful, all user needs met.
Safety regarding risk analysis	Implementation and effectiveness of all risk control requirements specified in the SeaSpine Navigation Adapter, Reference Clamp, Pedicle Probe risk analysis are tested and verified.	Risk Control requirements are effective and mitigate the associated risks to an acceptable level.
Product Safety standards	The SeaSpine Navigation Adapter, Reference Clamp, Pedicle Probe was tested to the following recognized standards: ISO 10993-1, and ISO 17665-1.	Compliance with recognized standards have been verified in the previous application. Previous test results have not been affected by this change.
Non-Clinical Accuracy	System's accuracy is tested using the SeaSpine Navigation Adapter, Reference Clamp, Pedicle Probe compatibility with the 7D Surgical System on phantom models following the ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems in addition to Target Registration Error.	All accuracy specifications have been met for the SeaSpine® Navigation Adapter, Reference Clamp, and Pedicle Probe. Accuracy testing for Universal Tracking / non-tracked surgical probe Array/Navigation Adapter assembly have been verified in previous application K192140 and K162375.

All non-clinical tests successfully passed demonstrating that the subject device performs as safely and effectively as the predicate device and supporting substantial equivalence.

9. Clinical Data

A clinical trial was not required to demonstrate that the SeaSpine 7D Navigation Instruments perform as safely and effectively as the predicate device. Clinical validation is unnecessary as the SeaSpine 7D Navigation Instruments introduce no new indications for use, and device features are equivalent to the previously cleared predicate device identified. The clinical safety and effectiveness of the SeaSpine 7D Navigation Instruments are historically accepted for both the predicate and subject device.

10. Conclusion

The SeaSpine 7D Navigation Instruments is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The predicate devices and The SeaSpine 7D Navigation Instruments use equivalent technologies.

The non-clinical verification and validation performed support the safety and effectiveness of The SeaSpine 7D Navigation Instruments compatibility and useability with the 7D Surgical System. The conclusions drawn from the non-clinical tests demonstrate that The SeaSpine 7D Navigation Instruments perform as safely and effectively as the legally marketed device according to the comparison based on the requirements of 21 CFR §882.4560 and the information provided herein. It is concluded that The SeaSpine 7D Navigation Instruments is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics, and performance characteristics.