August 31, 2023

Surgalign Spine Technologies
Jeremy Markovich
Senior Director, Regulatory Affairs
520 Lake Cook Road Suite 315
Deerfield, Illinois 60015

Re: K231611
Trade/Device Name: HOLO Portal™ Surgical Guidance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: June 1, 2023
Received: June 2, 2023

Dear Jeremy Markovich:

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,

FDA Tejen D. Soni -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)*
K231611

Device Name
HOLO Portal™ Surgical Guidance System

Indications for Use *(Describe)*
The HOLO Portal™ Surgical Guidance System is indicated as an aid for precisely locating anatomical structures in either open or percutaneous orthopedic procedures in the lumbosacral spine region. Their use is indicated for any medical condition of the lumbosacral spine in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the iliac crest, can be identified relative to intraoperative CT images of the anatomy.

The HOLO Portal™ Surgical Guidance System simultaneously displays 2D stereotaxic data along with a 3D virtual anatomy model over the patient during surgery. The stereotaxic display is indicated for continuously tracking instrument position and orientation to the registered patient anatomy while the 3D display is indicated for localizing the virtual instrument to the virtual anatomy model over the patient during surgery. The 3D display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed 2D stereotaxic information.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K231611

510(k) Summary: HOLO Portal™ Surgical Guidance System

Company: Surgalign Spine Technologies, Inc.

Contact: Alanna Joshi
Surgalign Spine Technologies, Inc.
520 Lake Cook Road Suite 315
Deerfield, IL 60015
630-227-3809

Date Prepared: August 31, 2023

Proprietary Name: HOLO Portal™ Surgical Guidance System

Common Name: Stereotaxic Instrument

Classification: 21 CFR 882.4560
Product Code(s): OLO, LLZ
Class II

Primary Predicate: ARAI Surgical Navigation System (K211254)

Indications for Use:
The HOLO Portal™ Surgical Guidance System is indicated as an aid for precisely locating anatomical structures in either open or percutaneous orthopedic procedures in the lumbosacral spine region. Their use is indicated for any medical condition of the lumbosacral spine in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the iliac crest, can be identified relative to intraoperative CT images of the anatomy.

The HOLO Portal™ Surgical Guidance System simultaneously displays 2D stereotaxic data along with a 3D virtual anatomy model over the patient during surgery. The stereotaxic display is indicated for continuously tracking instrument position and orientation to the registered patient anatomy while the 3D display is indicated for localizing the virtual instrument to the virtual anatomy model over the patient during surgery. The 3D display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed 2D stereotaxic information.

Device Description:
The HOLO Portal™ System is a combination of hardware and software that provides visualization of the patient's internal anatomy and surgical guidance to the surgeon based on patient-specific digital imaging.

HOLO Portal™ is a navigation system for surgical planning and/or intraoperative guidance during stereotactic surgical procedures. The HOLO Portal™ System consists of two mobile devices: 1)

the surgeon workstation, which includes the display unit and the augmented reality visor (optional), and 2) the control workstation, which houses the optical navigation tracker and the computer. The optical navigation tracker utilizes infrared cameras and active infrared lights to triangulate the 3D location of passive markers attached to each system component to determine their 3D positions and orientations in real time. Software algorithms combine tracking information and high-resolution 3D anatomical models to display representations of patient anatomy, compared to traditional two-dimensional (2D), displays during surgical procedures.

The following modifications have been applied to the previously cleared ARAI Surgical Navigation System (K211254):

Additional compatibility capabilities have been added to the system. Clearance of this 510(k) will allow the HOLO Portal System to be compatible with the following components:

- Ziehm Vision RFD 3D Scanner (K202360)
- GE OEC 3D Scanner (K203346)
- NDI Polaris Vega XT Camera

Summary of Technological Characteristics:
The modified HOLO Portal™ Surgical Guidance System has the same technological characteristics as its predicate device, the cleared ARAI Surgical Navigation System. Both systems have the same design, materials, performance characteristics, and the same or equivalent labeling. Both systems include very similar hardware and software components with the following basic components: software, optical tracking camera, single use passive reflective markers, rigid reference point, reusable instrument arrays, and 2D and 3D augmented reality (AR) display. The software in both systems is designed for real time calculation and display of spatial position of the tip of surgical instruments relative to patient's anatomy. The HOLO Portal™ System is comparable to the predicate in terms of intended use, fundamental scientific technology, technological characteristics, and principle of operation.

A table comparing the key features of the subject and predicate devices is provided below:

Comparison of the Principles of Operation and Technological Characteristics

Subject Device and Predicate Comparison

Features	**HOLO Portal™ System**	**ARAI™ Surgical Navigation System**
510(k) number	Subject Device	K211254
Product Code	OLO, LLZ	OLO, LLZ
Indications for Use	The HOLO Portal™ Surgical Guidance System is indicated as an aid for precisely locating anatomical structures in either open or percutaneous orthopedic procedures in the lumbosacral spine region. Their use is indicated for any medical condition of the lumbosacral spine in which the use of stereotactic surgery may be appropriate, an where reference to a rigid anatomical structure, such as the iliac crest, can be identified relative to intraoperative CT images of the anatomy. The HOLO Portal™ Surgical Guidance System simultaneously displays 2D stereotaxic data along with a 3D virtual anatomy model over the patient during surgery. The stereotaxic display is indicated for continuously tracking instrument position and orientation to the registered patient anatomy while the 3D display is indicated for localizing the virtual instrument to the virtual anatomy model over the patient during surgery. The 3D display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed 2D stereotaxic information.	The ARAI™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous orthopedic procedures in the lumbosacral spine region. Their use is indicated for any medical condition of the lumbosacral spine in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the iliac crest, can be identified relative to intraoperative CT images of the anatomy. The ARAI System simultaneously displays 2D stereotaxic data along with a 3D virtual anatomy model over the patient during surgery. The stereotaxic display is indicated for continuously tracking instrument position and orientation to the registered patient anatomy while the 3D display is indicated for localizing the virtual instrument to the virtual anatomy model over the patient during surgery. The 3D display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed 2D stereotaxic information.
User Population	Orthopedic surgeons or neurosurgeons	Orthopedic surgeons or neurosurgeons
Intended Use Environment	Operating room	Operating room
Main System Components	• AR glasses • Software application • Tracking camera • Single use passive reflective markers • Rigid reference point • Reusable instrument arrays • 2D and 3D augmented reality display	• AR glasses • Software application • Tracking camera • Single use passive reflective markers • Rigid reference point • Reusable instrument arrays • 2D and 3D augmented reality display
Modes of Operation	• Patient Preparation • System Set-up • Intraoperative Scan	• Patient Preparation • System Set-up • Intraoperative Scan

Features	**HOLO Portal™ System**	**ARAI™ Surgical Navigation System**
	• Scan Import • Patient Registration • Navigation	• Scan Import • Patient Registration • Navigation
View (Display Features)	• 2D axial, sagittal, and coronal • 3D anatomical model • Mesh Mode • 3D, 2D anatomic orthogonal planes • Trajectories • Trajectory guidance • Look Ahead • Instrument's tip view • Clipping tool • Image Intensity • 3D transparent • User defined • Implant • AR OFF (3D OFF)	• 2D axial, sagittal, and coronal • 3D anatomical model • Mesh Mode • 3D, 2D anatomic orthogonal planes • Trajectories • Trajectory guidance • Look Ahead • Instrument's tip view • Clipping tool • Image Intensity • 3D transparent • User defined • Implant • AR OFF (3D OFF)
Software operating principle	The HOLO Portal™ Software functionality is described in terms of its feature sets which are categorized as imaging modalities, registration, planning, interfaces with medical devices, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.	The ARAI Software functionality is described in terms of its feature sets which are categorized as imaging modalities, registration, planning, interfaces with medical devices, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.
Localization Technology and Tracker	Optical - infrared 6 DOF • NDI Polaris Vega XT Camera • OptiTrack V120: Trio	Optical - infrared 6 DOF • OptiTrack V120: Trio
Registration features	Automatic 3D Image Registration performed after placing a positional reference over the patient's anatomy and scanning the surgical field with an intraoperative scanner.	Automatic 3D Image Registration performed after placing a positional reference over the patient's anatomy and scanning the surgical field with an intraoperative scanner.
Segmentation and 3D model generation	Voxels of medical datasets (DICOM format) that correspond to the spine are automatically segmented and converted to a polygonal mesh for displaying purposes.	Voxels of medical datasets (DICOM format) that correspond to the spine are automatically segmented and converted to a polygonal mesh for displaying purposes.
Medical imaging rendering	Polygonal mesh	Polygonal mesh

Features	**HOLO Portal™ System**	**ARAI™ Surgical Navigation System**
Imaging Modality	X-Ray Based Imaging	X-Ray Based Imaging
Medical Device Interfaces	• O-arm Imaging System • Ziehm Vision RFD Scanner • GE OEC 3D Scanner	• O-arm Imaging System
Communication between Scanner and platform/ computer	Encrypted USB for DICOM	Encrypted USB for DICOM import & export with Medtronic O-arm
Display and Optics Technology	Augmented Reality using near eye see-through display; data displayed on patient's anatomy	Augmented Reality using near eye see-through display; data displayed on patient's anatomy

Performance Testing:

Verification and validation testing was conducted on HOLO Portal™ Surgical Guidance System to confirm that the device meets performance requirements under the indications for use and to ensure equivalent safety and efficacy of the system to the cited predicate device: Non-clinical testing included system, software, and instrument verification and validation to demonstrate that the system can consistently meet the user needs, corresponding design inputs, and intended use:

- Non-clinical system, software, and instrument verification and validation – demonstrated compliance with user needs and corresponding design inputs.
- Surgical simulations conducted on cadavers were performed for system validation. The positional displacement is measured as the 3D (Euclidean) distance between the tips of the virtual and real implants, and the angular axis displacement is measured as the angle between the 3D trajectories of the virtual and real implants.

  The worst-case 3D positional (measured in mm) and angular error (measured in degrees) between the real and virtual pedicle screws for performance validation is summarized below:

Performance Validation				
	Mean	Standard Dev.	95% CI Upper Bound	99% CI Upper Bound
Positional Error [mm]	2.37	0.72	2.58	2.69
Angular Error [degrees]	1.40	0.84	1.65	1.73

- Surgical simulations conducted on rigid benchtop phantoms were performed for system verification. Phantoms were scanned, registered, and screws were placed using standard clinical workflows to verify the system accuracy and precision by removing the variation due to anatomical movements relative to the reference fixation. The worst-case 3D positional (measured in mm) and angular error (measured in degrees) between the real and virtual pedicle screws for performance verification is summarized below:

Performance Verification			
	Mean	Standard Dev.	95% CI Upper Bound
Positional Error [mm]	1.54	0.74	1.75
Angular Error [degrees]	1.50	0.68	1.69

- Additionally, bench top testing included subsystem testing per ASTM F2554-18.
- Augmented Reality technical characteristics were demonstrated via performance testing of display latency and framerate, stereoscopic crosstalk, and spatial accuracy (a measurement of disparity between the visualization of a real and virtual objects) under varying user conditions.
- Compliance conformity assessments per:
  1. IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance
  2. IEC 60601-1-2 Medical electrical equipment. General requirements for basic safety and essential performance – Electromagnetic disturbances

Biocompatibility:
The biocompatibility evaluation for HOLO Portal™ Surgical Guidance System has been conducted in accordance with FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process'," June 16, 2016. The evaluation confirms that HOLO Portal™ System meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:
Testing was performed to assure compliance with recognized safety standard, IEC 60601-1:2005, AMD1:2012, AMD2:2020, and standard for electrical safety and electromagnetic compatibility, IEC 60601-1-2:2020 Ed 4.1.

Software Verification and Validation Testing:
Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

A set of test samples presenting lumbosacral spine, extracted from stationary and intraoperative Computed Tomography scans was subjected to the autonomous spine segmentation process performed by the HOLO Portal System. The quality of the autonomous anatomical segmentation applied by the HOLO Portal System was determined by comparing it with manual segmentations prepared by trained analysts based on mean Sørensen–Dice coefficient (DSC) calculations.

Basis of Substantial Equivalence:
HOLO Portal™ System has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports the substantial equivalence to the cited predicate device.