January 14, 2022

Surgalign Spine Technologies
Cristian Luciano
Vice President of Research and Development
520 Lake Cook Road, Suite 315
Deerfield, Illinois 60015

Re: K211254
Trade/Device Name: ARAI Surgical Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: December 14, 2021
Received: December 15, 2021

Dear Cristian Luciano:

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,

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)*
K211254

Device Name
ARAI™ Surgical Navigation System

Indications for Use *(Describe)*
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.

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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K211254

510(k) Summary: ARAI™ Surgical Navigation System

Company: HOLO SURGICAL, INC.
(a subsidiary of Surgalign Spine Technologies)

Contact: Cristian Luciano, PhD
Surgalign Spine Technologies
520 Lake Cook Road Suite 315
Deerfield, IL 60015
630-227-3809

Date Prepared: January 14, 2022

Proprietary Name: ARAI™ Surgical Navigation System

Common Name: Stereotaxic Instrument

Classification: 21 CFR 882.4560, 892.2050
Product Code(s): OLO, LLZ
Class II

Primary Predicate: StealthStation S8 Spine Software V1.0.0 (K170011)

Reference Devices(s): OpenSight (K172418)
xvision Spine (K190929)
Streamline Navigated Instruments (K200095)
Streamline TL Spinal Fixation System (K192800)
Streamline MIS Spinal Fixation System (K192396)

Purpose:
The purpose of this submission is to request clearance of the HoloSurgical® ARAI™ Surgical Navigation System in either open or percutaneous orthopedic spine pedicle screw procedures.

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

ARAI™ is a navigation system for surgical planning and/or intraoperative guidance during stereotactic surgical procedures. The ARAI™ 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. The 3D scanned data is displayed with both 2D images and 3D virtual models along with tracking information on computer monitors mounted on workstations near the patient bed and a dedicated projection display mounted over the patient. Augmented reality is accomplished with the 3D virtual models being viewed with dedicated headset(s).

Software algorithms combine tracking information and high-resolution 3D anatomical models to display representations of patient anatomy.

Indications for Use:
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.

Technological Characteristics:
The ARAI™ System has the same design, materials, performance characteristics, and the same or equivalent labeling. The ARAI™ System is comparable to the predicate in terms of intended use, fundamental scientific technology, technological characteristics, and principle of operation.

Comparison of the Principles of Operation and Technological Characteristics

Device	**ARAI™ Surgical Navigation System**	**StealthStation S8 with Spine Software V1.0.0 (Predicate Device)**	**OpenSight (Reference Device)**	**xvision Spine (Reference Device)**
510(k) number	Subject Device	K170011	K172418	K190929
Product code	OLO, LLZ	OLO	LLZ	OLO
Indications for Use	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	The StealthStation System, with StealthStation Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. Their use 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 the spine or pelvis, can be identified relative to images of the anatomy. This can include the following spinal implant procedures, such as: • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement	OpenSight is intended to enable users to display, manipulate, and evaluate 2D, 3D, and 4D digital images acquired from CR, DX, CT, MR, and PT sources. It is intended to visualize 3D imaging holograms of the patient, on the patient, for preoperative localization and pre-operative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation. OpenSight is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the same anatomy of the patient in order to support pre-operative analysis. OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures. OpenSight is intended for use by trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The device assists doctors to better understand anatomy and pathology of patient.	The xvision Spine System, with xvision Spine System Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. Their use 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 the spine, can be identified relative to CT imagery of the anatomy. This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region. The Headset of the xvision Spine System displays 2D stereotaxic screens and a virtual anatomy screen. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient imagery. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning. The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

Device	**ARAI™ Surgical Navigation System**	**StealthStation S8 with Spine Software V1.0.0 (Predicate Device)**	**OpenSight (Reference Device)**	**xvision Spine (Reference Device)**
	displayed 2D stereotaxic information.			
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)	• Look Sideways • 3D • Anatomic orthogonal • Trajectory 1 and 2 • Trajectory Guidance • Look Ahead • Probe's Eye • AP and Lateral • Synthetic AP and Lateral • Maximum Intensity Projection (MIP) • Video input	• Normal Mode • Volume Mode • Alignment Mode • Slice Mode	• 2D images: axial and sagittal • 3D anatomical model • Trajectories • Trajectory guidance • Instrument's tip view • 3D transparent • 3D OFF (only 2D) • 3D follow instrument movement
Software operating principle	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.	StealthStation Spine 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.	OpenSight uses the HoloLens technology to register scanned images over the patient when user has OpenSight headset on and in use. This allows the user to both see the patient and through them, with dynamic holograms of the patient's internal anatomy. OpenSight tools/features include window level, segmentation and rendering, registration, motion correction, virtual tools, alignment, and the capability to measure distance and image intensity values, such as standardized uptake value. OpenSight displays measurement lines, annotations, and regions of interest. 3D images	Xvision Software receives the intraoperative 3D scanner images and calculates the registration between the patient's anatomy and the acquired intraoperative images. It then receives tracking information and displays tracked virtual images of the surgical instrument aligned with the patient on the computer monitor. The optical tracker is embedded into the headset.

Device	**ARAI™ Surgical Navigation System**	**StealthStation S8 with Spine Software V1.0.0 (Predicate Device)**	**OpenSight (Reference Device)**	**xvision Spine (Reference Device)**
			include but not limited to tumors, masses, appendices, heart, kidney, bladder, stomach, blood vessels, arteries, and nerves.	
Patient and surgical instruments tracking method	Optical - infrared 6 DOF	Optical - infrared 6 DOF	Optical - infrared environment scanning described as HoloLens spatial mapping, process of mapping real-world surfaces into the virtual world.	Optical - infrared 6 DOF
Registration features	Automatic 3D Image Registration performed after securely placing a device with passive reflective markers over the patient's anatomy and scanning the surgical field with an intraoperative scanner.	PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image Registration Automatic 3D Image Registration	Registration does not require infrared tracking devices or other fiducials in order to perform registration. Registration of the patient (reality) to another image data set such as MRI or CT (augmented reality) are performed by the OpenSight device which contains infrared ranging cameras which can map the surface geometry of an object creating a mesh of triangles conforming to whatever the object is. This can include the patient, the surrounding room, the table, etc. The resolution of the mesh is controlled by the device. For mapping a large object such as a room, a larger mesh would be utilized. Surface geometry mapping of a patient's anatomy utilizes the maximum resolution of the device while the user may walk around the object in a 360° circle mapping the object from many views in order to obtain the best localization in space.	Automatic 3D Image Registration performed after placing a device with passive reflective markers over the patient's anatomy and scanning the surgical field with an intraoperative scanner.

Device	**ARAI™ Surgical Navigation System**	**StealthStation S8 with Spine Software V1.0.0 (Predicate Device)**	**OpenSight (Reference Device)**	**xvision Spine (Reference Device)**
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.	3D anatomical structures are segmented from diagnostic CT scans are imported as a DICOM file format to provide a direct visualization of the patient's anatomy.	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.	Both polygonal mesh and volumetric rendering of the spine are shown.	Both polygonal mesh, volumetric, and slice rendering include but not limited to tumors, masses, appendices, heart, kidney, bladder, stomach, blood vessels, arteries, and nerves.	Both polygonal mesh and volumetric rendering of the spine are shown.
Communication between Scanner and platform/ computer	Encrypted USB for DICOM import & export with Medtronic O-arm	Network Connectivity, CD, DVD, USAB, DICOM Import, DICOM Export	WiFi communication with Novorad server, not a scanner	USB & LAN connectivity using DICOM

Performance Testing:
Verification and validation testing was conducted on ARAI™ Surgical Navigation 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 devices:

- 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 overall 3D positional error measured in [mm] between the real and virtual pedicle screws for performance validation is summarized below:

Performance Validation	Positional Error [mm]			
	Mean	Standard deviation	95% CI Upper Bound	99% CI Upper Bound
ARAI System	2.16	1.00	2.41	2.49

  The overall 3D angular error measured in degrees between the real and virtual pedicle screws for performance validation is summarized below:

Performance Validation	Angular Error [degrees]			
	Mean	Standard deviation	95% CI Upper Bound	99% CI Upper Bound
ARAI System	1.49	0.73	1.68	1.74

  Additionally, bench top testing included tracking accuracy testing using phantoms and subsystem testing per ASTM F2554-18.
- Augmented Reality technical characteristics were demonstrated via performance testing of display luminance, image contrast, latency and framerate, stereoscopic crosstalk and contrast, AR shutter frequency, and spatial accuracy (a measurement of disparity between the visualization of a real and virtual objects) under varying user conditions.
- Human factors and usability testing was conducted to evaluate the user interface and the system display in the intended user environment.
- 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
  3. IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability

Biocompatibility:
The biocompatibility evaluation for ARAI™ Surgical Navigation 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 ARAI™ Surgical Navigation System meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:
Testing was performed to assure compliance with recognized safety standard, IEC 60601-1:2012 standard for electrical safety and electromagnetic compatibility, IEC 60601-1-2:2014.

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 ARAI Spine Software. The quality of the autonomous anatomical segmentation applied by the ARAI Surgical Navigation 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:
ARAI™ Surgical Navigation System has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The reference predicate devices were relied upon to identify applicable test methods associated with AR technology. The information provided within this premarket notification supports the substantial equivalence to the cited predicate devices.