September 29, 2022

Surgical Theater, Inc.
Kevin Murrock
Sr. Director of Quality and Regulatory
30559 Pinetree Road, Suite 206
Pepper Pike, Ohio 44124

Re: K213034
Trade/Device Name: SpineAR SNAP
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: August 26, 2022
Received: August 30, 2022

Dear Kevin Murrock:

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, 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)*
K213034

Device Name
SpineAR SNAP

Indications for Use *(Describe)*

SpineAR SNAP is intended for use for pre-operative surgical planning on-screen and in a virtual environment, and intra-operative surgical planning and visualization on-screen and in an augmented environment using the HoloLens2 and Magic Leap 1 AR headset displays with validated navigation systems as identified in the device labeling.

SpineAR SNAP is indicated for spinal stereotaxic surgery, and where reference to a rigid anatomical structure, such as the spine, can be identified relative to images of the anatomy. SpineAR is intended for use in spinal implant procedures, such as Pedicle Screw Placement, in the lumbar and thoracic regions with the Magic Leap 1 AR headset, and in the lumbar region with the HoloLens2 AR headset.

The virtual 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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510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: 27-Sep-2022

Manufacturer/Submitter:

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Contact Person:

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Name of Device

- Trade Name: SpineAR SNAP
- Common Name: Augmented Reality System
- Classification Name: Orthopedic Stereotaxic Instrument
- Regulation Number: 21 CFR 882.4560
- Product Code: OLO
- Regulatory Classification: II
- Device Panel: Orthopedic

Predicate Device

Device Name: StealthStation™ S8 Spine Software v1.3.0
Manufacturer: Medtronic Navigation, Inc.
510(k) Number: K201189

Reference Device

Device Name: Surgical Navigation Advanced Platform (SNAP)
Manufacturer: Surgical Theater, Inc.
510(k) Number: K160584

Indications for Use:

SpineAR SNAP is intended for use for pre-operative surgical planning on-screen and in a virtual environment, and intra-operative surgical planning and visualization on-screen and in an augmented environment using the HoloLens2 and Magic Leap 1 AR headset displays with validated navigation systems as identified in the device labeling.

SpineAR SNAP is indicated for spinal stereotaxic surgery, and where reference to a rigid anatomical structure, such as the spine, can be identified relative to images of the anatomy. SpineAR is intended for use in spinal implant procedures, such as Pedicle Screw Placement, in the lumbar and thoracic regions with the Magic Leap 1 AR headset, and in the lumbar region with the HoloLens2 AR headset.

The virtual 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 SpineAR SNAP does not require any custom hardware and is a software-based device that runs on a high-performance desktop PC assembled using "commercial off-the-shelf" components that meet minimum performance requirements.

The SpineAR SNAP software transforms 2D medical images into a dynamic interactive 3D scene with multiple point of views for viewing on a high-definition (HD) touch screen monitor. The surgeon prepares a pre-operative plan for stereotaxic spine surgery by inserting guidance objects such as directional markers and virtual screws into the 3D scene. Surgical planning tools and functions are available on-screen and when using a virtual reality (VR) headset. The use of a VR headset for preoperative surgical planning further increases the surgeon's immersion level in the 3D scene by providing a 3D stereoscopic display of the same 3D scene displayed on the touch screen monitor.

By interfacing to a 3rd party navigation system such as a Medtronic StealthStation S8, the SpineAR SNAP extracts the navigation data (i.e. tool position and orientation) and presents the navigation data into the advanced interactive, high quality 3D image, with multiple point of views on a high-definition (HD) touch screen monitor. Once connected, the surgeon can then execute the plan through the intra-operative use of the SpineAR SNAP's enhanced visualization and guidance tools.

The SpineAR SNAP supports three (3) guidance options from which the surgeon selects the level of guidance that will be shown in the 3D scene. The guidance options are dotted line (indicates deviation distance), orientation line (indicates both distance and angular deviation), and ILS (indicates both distance and angular deviation using crosshairs). Visual color-coded cues indicate alignment of the tracker tip to the guidance object (e.g. green = aligned).

The 3D scene with guidance tools can also be streamed into an AR wireless headset (Magic Leap 1 or HoloLens2) worn by the surgeon during surgery. The 3D scene and guidance shown within the AR headset is projected above the patient and does not obstruct the surgeons view of the surgical space.

Summary of Technological Characteristics

The SpineAR SNAP is similar in its technological features to its predicate device, the StealthStation S8 Spine Software v1.3.0 (K201189). Both systems are indicated for spinal stereotaxic surgery, and where reference to a rigid anatomical structure, such as the spine, can be identified relative to images of the anatomy.

The SpineAR SNAP does not include any of the physical stereotaxic instrumentation, including camera system, and relies on the positional information supplied by the connected navigation system (e.g. Medtronic StealthStation S8 system with StealthStation Spine Software v1.3.0) to track the position of the surgical instruments relative to the surgical anatomy.

The SpineAR SNAP includes an AR headset that displays the 2D images and 3D scene including navigation and enhanced guidance information in an AR wireless headset (e.g. Microsoft HoloLens2) worn by the surgeon. The predicate device displays 2D and 3D images including navigation information with minimal guidance on a system monitor, and does not support use of AR headset.

The following table compares the key features of the subject and predicate devices:

Feature	**Subject Device: Spine*AR* SNAP**	**Predicate Device: StealthStation S8 Spine Software v1.3.0**	**Reference Device: Surgical Navigation Advanced Platform (SNAP)**
Indications for Use	SpineAR SNAP is intended for use for pre-operative surgical planning on-screen and in a virtual environment, and intra-operative surgical planning and visualization on-screen and in an augmented environment using the HoloLens2 and Magic Leap 1 AR headset displays with validated navigation systems as identified in the device labeling. SpineAR SNAP is indicated for spinal stereotaxic surgery, and where reference to a rigid anatomical structure, such as the spine, can be identified relative to images of the anatomy. SpineAR is intended for use in spinal implant procedures, such as Pedicle Screw	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 stereotaxic 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: o Pedicle Screw Placement o Iliosacral Screw Placement o Interbody Device Placement	The SNAP is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT or MR scanner to an output file. It is also intended for use in simulating and evaluating surgical treatment options both pre-operatively and intra-operatively with validated systems as identified in the device labeling.

Feature	**Subject Device:** **Spine*AR* SNAP**	**Predicate Device:** **StealthStation S8 Spine Software v1.3.0**	**Reference Device:** **Surgical Navigation Advanced Platform (SNAP)**
	Placement, in the lumbar and thoracic regions with the Magic Leap 1 AR headset, and in the lumbar region with the HoloLens2 AR headset. The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed 2D stereotaxic information.		
Main system components	• Cart with computer, touchscreen monitor, UPS and input devices. • Software application • AR Headset • VR Headset	• Platform including cart, computer, monitor and tracking cameras • Software application • Reflective markers - Spheres • Accessories (Instrument adaptors, referencing system)	• Cart with computer, touchscreen monitor and input devices. • Software application • VR Headset
System Accuracy Requirements	Provided by the connected 3rd party navigation system as the subject device does not include a camera system or tracking arrays. Maintains the system accuracy of the connected navigation system. 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.	Under representative worst-case Configuration, the StealthStation S8 Spine software v1.3.0, has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees. Mean Accuracy Values (StealthAiR Spine): Positional Error – 1.01 mm Trajectory Error – 0.37 degrees Mean Accuracy Values (Overlapping Slices): Positional Error – 0.51 mm Trajectory Error –0.41 degrees	Provided by the connected 3rd party navigation system as the subject device does not include a camera system or tracking arrays.
Imaging Modalities	CT, MR and XA	X-Ray Based Imaging	CT, MR and XA
Registration Features	All registration is performed by the connected 3rd party navigation system.	• PointMerge Registration • SurfaceMerge Registration	All registration is performed by the connected 3rd party navigation system.

Feature	**Subject Device:** **SpineAR SNAP**	**Predicate Device:** **StealthStation S8 Spine Software v1.3.0**	**Reference Device:** **Surgical Navigation Advanced Platform (SNAP)**
		• FluoroMerge Registration • Automatic 2D Image Registration • Automatic 3D Image Registration • StealthAiR Spine Automatic Registration	
Planning Features	• Plan Entry and Target Selection • 3D Model Building • Directional Markers	• Plan Entry and Target Selection • 3D Model Building • Deformity Planning	• Plan Entry and Target Selection • 3D Model Building
Medical Device Interfaces	The system does not interface directly with the imaging modality device.	• O-arm Imaging System • Ziehm Vision FD Vario 3D C-Arm • ISO-C 3D C-Arm • Ziehm Vision RFD 3D C-arm • Stealth-Midas MR8 • Orbic 3D C-Arm	The system does not interface directly with the imaging modality device.
Localization Technology	The subject device does not include a camera system or tracking arrays, but instead relies on the stereotaxic guidance provided from a connected 3rd party navigation system to track patient anatomy and surgical tools.	Optical (infra-red)	The subject device does not include a camera system or tracking arrays, but instead relies on the stereotaxic guidance provided from a connected 3rd party navigation system to track patient anatomy and surgical tools.
Connection to 3rd party surgical navigation system to track patient anatomy and surgical tools.	Yes. Medtronic StealthStation S8 Spine Software v1.3.0	No	Medtronic StealthStation S8 Cranial Version 1.3.0-49 and Brainlab Cranial Version 2.1
Capability of creating 3D models of patient data from 2D scan slices.	Yes	Yes	Yes
Virtual Reality (VR) Headset Display for Pre-Operative Use	Yes	No	Yes
Augmented Reality (AR) Headset Display for Intra-operative Use	Yes	No	No
Intra-operative visualization and guidance tools shown on a wireless AR headset display.	Yes	No	No

Feature	Subject Device: SpineAR SNAP	Predicate Device: StealthStation S8 Spine Software v1.3.0	Reference Device: Surgical Navigation Advanced Platform (SNAP)
Visual Guidance Options with color-coded cues.	1) Dotted Line 2) Orientation Line 3) ILS	No	No

The differences between the subject and predicate device do not raise any new questions regarding safety and effectiveness. Based on the information provided in this 510(k) submission, the SpineAR SNAP is considered substantially equivalent to the predicate device in terms of fundamental scientific technology.

Performance Data

The following non-clinical performance testing was conducted to evaluate the subject device to ensure the SpineAR SNAP meets its intended use and performance requirements.

- Software Verification and Validation was performed to test the software requirements specifications for the SpineAR SNAP.
- Human Factors and Usability Validation demonstrated that the intended users of a SpineAR SNAP can safely and effectively perform tasks for the intended uses in the expected use environments, i.e. intraoperative use of the AR headsets. Validation took place under conditions of simulated use with users providing feedback on the usability of the software for performing defined tasks.
- Navigation Accuracy testing was conducted to demonstrate that SpineAR does not negatively affect the navigation accuracy of the connected Medtronic StealthStation 8 surgical navigation system. The final placement of each screw in a spine model was assessed via a post-surgical CT scan and compared to the pre-surgical plan to calculate the absolute displacement of the screw tip and absolute angular error of the screw. The summary of accuracy test results below demonstrate performance in 3D positional and trajectory accuracy that is within the system accuracy of the StealthStation S8 (mean positional error $\leq$ 2.0 mm and mean trajectory error of $\leq$ 2°):
  - Mean Positional/Displacement Error: 1.02 mm
  - Max Positional/Displacement Error: 2.80 mm
  - Mean Trajectory/Angular Error: 1.79°
  - Max Trajectory/Angular Error: 3.00°
- Verification of virtual screw library by verifying the length and diameter (e.g. 40 mm x 5.5 mm) of virtual screws shown in the 3D model accurately represent the real screws used during surgery, and screws are accurately positioned at the tip of the tracked tool.
- Performance of the Headset display was demonstrated by verifying the following elements: Field of View (FOV), resolution, luminance, transmittance, distortion, contrast ratio, temporal, display noise and motion-to-photon latency.

- Projection latency testing was performed to assess the time delay between movement of a navigated handheld instrument and its display in the scene shown in the Magic Leap 1 and Microsoft HoloLens2 AR headsets. Based on experience with other types of simulators and feedback from surgeons during usability testing, a time delay requirement of < 250 ms was established. The summary of latency test results below demonstrates the projection delay for both AR headsets is acceptable:
    - Average Delay: 195 ms for HoloLens2 and 195 ms for Magic Leap 1
    - Worst Case Delay: 231 ms for HoloLens2 and 231 ms for Magic Leap 1
- Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1-2:2014+A1:2020 for all system components including both the Magic Leap 1 and Microsoft HoloLens2 AR headsets.
- Wireless coexistence was evaluated and tested per AAMI TIR69: 2017/(R)2020 and ANSI IEEE C63.27-2017.

Performance data demonstrated the SpineAR SNAP functions as intended without raising new safety or effectiveness issues, and does not impact accuracy or clinical workflow. The test results support a finding that the SpineAR SNAP is substantially equivalent to the predicate StealthStation S8 Spine Software v1.3.0.

Substantial Equivalence Conclusion

The SpineAR SNAP is substantially equivalent to the StealthStation™ S8 Spine Software v1.3.0. The SpineAR SNAP has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate device. Any differences between the subject and predicate device do not raise any new concerns regarding safety and effectiveness.