December 24, 2024

Surgical Theater, Inc.
Kevin Murrock
Sr. Director of Quality & Regulatory
23645 Mercantile Road
Suite M
Beachwood, Ohio 44122

Re: K243623
Trade/Device Name: SpineAR SNAP (SyncAR Spine)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: SBF, LLZ
Dated: November 21, 2024
Received: November 25, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K243623

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 and HoloLens2 AR headsets.

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.

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

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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: 23-Dec-2024

510(k) Type: Special 510(k) for Device Modification

Manufacturer/Submitter:

Surgical Theater, Inc.
23645 Mercantile Road, Suite M
Beachwood, Ohio 44122
Phone: (330) 472-6520

Establishment Registration Number: 3010197287

Contact Person:

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Phone: (330) 472-6520
Email: kmurrock@surgicaltheater.com

Name of Device

- Trade Name: SpineAR SNAP
- Other Device Trade Names: SyncAR Spine
- Common Name: Augmented Reality System
- Classification Name: Orthopedic Stereotaxic Instrument
- Regulation Number: 21 CFR 882.4560
- Product Code: SBF, LLZ
- Regulatory Classification: II
- Device Panel: Orthopedic

Predicate Device

Device Name: SpineAR SNAP
Manufacturer: Surgical Theater, Inc.
510(k) Number: K213034

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 surgeon's view of the surgical space.

Intended Use / 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 and HoloLens2 AR headsets.

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.

Summary of Technological Characteristics

The modified SpineAR SNAP has identical technological characteristics, principle of operation, and intended use of the predicate device. No design changes are included in the device modification for this 510(k) submission as only non-clinical performance testing was necessary to support the expanded indications for use of the SpineAR SNAP with the HoloLens2 AR headset from spinal implant procedures in lumbar region only to also include spinal implant procedures in thoracic region.

The following table is a comparison of the technological characteristics of the subject and predicate devices included in the scope of this 510(k).

Feature	**Predicate Device: Spine*AR* SNAP**	**Subject Device: Spine*AR* SNAP**
Manufacturer	Surgical Theater, Inc.	Surgical Theater, Inc.
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	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 *and HoloLens2 AR headsets*. 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.

Feature	**Predicate Device:** **Spine*AR* SNAP**	**Subject Device:** **Spine*AR* SNAP**
	the displayed 2D stereotaxic information.	
Magic Leap 1 Intra-operative Indications for Use	Spinal implant procedures, such as Pedicle Screw Placement, in both the lumbar and thoracic regions.	Spinal implant procedures, such as Pedicle Screw Placement, in both the lumbar and thoracic regions.
HoloLens2 Intra-operative Indications for Use	Spinal implant procedures, such as Pedicle Screw Placement, in the lumbar region only.	Spinal implant procedures, such as Pedicle Screw Placement, in *both* the lumbar and thoracic regions.

Performance Data

Performance testing was conducted to demonstrate the SpineAR with HoloLens2 AR headset is substantially equivalent to the use of the Magic Leap 1 AR headset cleared in the predicate SpineAR SNAP when performing spinal implant procedures in the thoracic region. 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 and absolute angular error of the screw. The HoloLens2 navigation accuracy test results in Table 1 demonstrate performance in 3D positional and trajectory accuracy that meets the accuracy of the predicate SpineAR SNAP using the Magic Leap 1 AR headset.

Table 1 - Performance Test Results: Accuracy of Pedicle Screw Placement in Thoracic Region

	Accuracy Requirement	**Magic Leap 1 AR Headset Results**	**HoloLens2 AR Headset Results**
Mean Positional/Displacement Error	≤ 2.0 mm	1.04 mm	0.76 mm
Max Positional/Displacement Error	≤ 3.0 mm	1.90 mm	1.47 mm
Mean Trajectory/Angular Error	≤ 2°	1.92°	1.73°
Max Trajectory/Angular Error	≤ 3°	2.80°	2.96°

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 use of the HoloLens2 AR headset in the subject device is substantially equivalent to the use of the Magic Leap 1 AR headset in the predicate SpineAR SNAP when performing spinal implant procedures in the thoracic region.

Substantial Equivalence Conclusion

The SpineAR SNAP is substantially equivalent to its predicate. Both the subject and predicate devices have identical intended use, technological characteristics, and principles of operation. The indications for use are similar with the only difference being the expanded use of the HoloLens2 AR headset for spinal implant procedures in the thoracic region. Previously the use of the HoloLens2 was only indicated for spinal implant procedures in the lumbar region, while the Magic Leap 1 AR headset was indicated for use in both the lumbar and thoracic regions. The modified indications for use did not require any design change, only the acquisition of additional performance data supporting the use of the HoloLens2 with SpineAR for spinal implant procedures in the thoracic region.

Any differences between the subject and predicate device do not raise any new concerns regarding safety and effectiveness, and performance testing demonstrates that the subject device is at least as safe and effective as the predicate device, and functions as intended.