



September 29, 2025

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

Re: K252054
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: June 30, 2025
Received: July 1, 2025

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252054

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Please provide the device trade name(s).

?

SpineAR SNAP (SyncAR Spine)

Please provide your Indications for Use below.

?

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 AR headset display 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 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) SUMMARY

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

Date Prepared: 29-Sept-2025

510(k) Type: Traditional 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:

Kevin M. Murrock
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Beachwood, Ohio 44122
Phone: (330) 472-6520
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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: K243623

1. 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 SpineAR SNAP is capable of projecting all the live navigated and guidance information into an AR headset such as the Microsoft HoloLens2 that is worn by the surgeon during surgery. When activated, the surgeon sees a projection of the 3D model along with the optional live navigated DICOM (Floating DICOM) and guidance cues. This AR projection is placed above, not directly over the patient in order to not impede the surgeon’s field of view, but still allow the surgeon to visualize all the desired information (navigation tracker, DICOM images, guidance data) while maintaining their focus on the patient and the surgical field of view (see Figure 1).

SpineAR Software Version SPR.2.0.0 incorporates AI/ML-enabled vertebra segmentation into the clinical workflow to optimize the preparation of a spine surgical plan for screw placement and decompression. The use of the AI/ML device software function is not intended as a diagnostic tool, but as visualization tool for surgical planning.

The use of AI/ML-enabled vertebrae segmentation streamlines the initial processing stage by generating a segmented poly object of each volume-rendered vertebra that requires only minimal to no manual processing, which may significantly reduce the overall processing time.

2. 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 AR headset display 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 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.

3. Summary of Technological Comparison to Predicate

SpineAR SNAP was compared to its predicate device in intended use, indications for use, design, function, and technology and it was demonstrated that they are substantially equivalent. Any technological differences within this 510(k), between the subject and predicate devices, do not impact substantial equivalence, or safety and effectiveness.

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

Feature	<u>Predicate Device:</u> SpineAR SNAP	<u>Modified Device:</u> SpineAR SNAP	Explanation of Differences
Manufacturer	Surgical Theater, Inc.	Surgical Theater, Inc.	Same
510(k) Number	K243623	K252054	NA

Feature	Predicate Device: SpineAR SNAP	Modified Device: SpineAR SNAP	Explanation of Differences
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.	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 AR headset display 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 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.	Magic Leap 1 AR headset is no longer supported by the manufacturer.
Main system components	• Cart with computer, touchscreen monitor, UPS and input devices. • Software application • AR Headset • VR Headset	Same	NA
Augmented Reality (AR) Headset Display for Intraoperative Use	• Magic Leap 1 • HoloLens2	HoloLens2	Magic Leap 1 AR headset is no longer supported by the manufacturer.

Feature	Predicate Device: SpineAR SNAP	Modified Device: SpineAR SNAP	Explanation of Differences
Intraoperative visualization and guidance tools shown on a wireless AR headset display.	Yes	Same	NA
Visual Guidance Options with color-coded cues.	1) Dotted Line 2) Orientation Line 3) ILS	Same	NA
Connection to 3rd party surgical navigation system to track patient anatomy and surgical tools.	Yes. Medtronic StealthStation S8 Spine Software v1.3.0	Same	NA
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.	Same	NA
Registration Features	All registration is performed by the connected 3 rd party navigation system.	Same	NA
Medical Device Interfaces	The system does not interface directly with the imaging modality device.	Same	NA
Imaging Modalities	CT, MR and XA	Same	NA
Import Intraoperative CT Scan	Transfer intraoperative registered CT scan via portable media such as secure flash drive.	Download intraoperative registered CT scan directly from Medtronic StealthStation S8.	This change does not impact the intended purpose nor does it raise questions of safety and performance since development, design verification, and validation processes are the same for both devices.

Feature	Predicate Device: SpineAR SNAP	Modified Device: SpineAR SNAP	Explanation of Differences
Spine-specific Advanced Algorithm Planning Features	None	- AI/ML-enabled vertebra segmentation - Pedicle Screw Planning - Segmental Fusion to align/fuse the segmented vertebra objects to the intraoperative CT scan.	Enhancements in the clinical workflow from the use of advanced algorithms does not impact the intended purpose nor does it raise questions of safety and performance since development, design verification, and validation processes are the same for both devices.

4. AI-Enabled Device Software Function

SpineAR Software Version SPR.2.0.0 includes AI/ML-enabled vertebra segmentation into workflow for preparing a surgical plan for screw placement and decompression. The use of the AI/ML function is not intended as a diagnostic tool.

1. Description of Class of Model

The core of the system is a 3D U-Net, a type of neural network architecture that excels at medical image segmentation. The algorithm processes the scan iteratively, patch by patch, from the bottom upwards.

A key feature is its use of a "memory" channel. As each vertebra is segmented, it is added to this memory channel. This informs the model of what has already been found, preventing it from re-segmenting the same vertebra and guiding it to the next one in the sequence. This iterative approach allows the model to accurately segment every vertebra separately, using a single, robust process.

2. Description of the Development Datasets

The model was trained from datasets independent from the performance validation datasets.

CT Vertebrae Model Development: The model for CT vertebrae segmentation was developed using a large, combined dataset to maximize diversity.

- **Data Sources:** The training data was aggregated from two independent, publicly-available academic datasets: VerSe 2020, TotalSegmentator.
- **Sample Size:** A total of 1,244 scans were used for model development (training and tuning).
- **Representativeness:** This dataset includes scans from multiple clinical centers. The data was intentionally chosen to be highly heterogeneous, covering a wide variety of patient ages, pathologies (including metastases and fractures), and scanner models.

CT Sacrum Model Development: The separate model for sacrum segmentation was developed using a specific subset of data.

- **Data Source:** The model was trained using relevant scans from the TotalSegmentator dataset which included sacrum ground-truth data.
- **Sample Size:** A total of 430 scans were used for model development.

MRI Vertebrae Model Development: The model for MRI segmentation was developed using a dataset specifically focused on the lumbar spine.

- **Data Source:** The model was trained on the publicly available SPIDER dataset.
- **Sample Size:** A total of 348 scans were used for model development.
- **Representativeness:** The data was collected from four different hospitals in the Netherlands and is representative of an adult population presenting with lower back pain.

3. Description of the Performance Validation Datasets

The performance of each of the AI models was tested using a separate subset of the data. These datasets were not used during model training or tuning, ensuring an objective assessment of the final model's performance.

CT Performance Validation

- **Data Sources:** The validation set was composed of the entire Spine-Mets-CT-SEG dataset and the original test set from the VerSe dataset. This was done to test the model on a varied, heterogeneous set of data.
- **Sample Size:** Performance was validated on a set of 95 scans from 92 unique patients.
- **Representativeness:** The test set was diverse, with 60% of scans from the United States and 40% from Europe. It included a balanced distribution of patient sex, a wide age range (18-90), and data from three major scanner manufacturers (Siemens, Philips, GE).
- **Sacrum Validation:** Sacrum segmentation was validated on a separate set of 38 scans from the TotalSegmentator dataset that was reserved exclusively for testing.

MRI Performance Validation

- **Data Source:** A portion of the SPIDER dataset was set aside and used exclusively for performance validation.
- **Sample Size:** Performance was validated on a set of 31 scans from 15 unique patients.
- **Representativeness:** The test set included data from both Philips and Siemens scanners and a balanced distribution of male and female patients

4. Description of the Statistical Confidence Level of Predictions

The primary metric used to measure segmentation accuracy is the **Mean Dice Coefficient (MDC)**. This score measures the degree of overlap between the AI's segmentation and the ground truth segmentation provided by expert radiologists.

- An MDC score of **1.0** represents a perfect match.
- An MDC score of **0.0** represents no overlap.

For this device, the pre-specified acceptance criterion for performance was that the lower bound of the 95% confidence interval for the MDC must be **above 0.8**.

CT Segmentation Performance Results

The AI model for CT scans demonstrated high accuracy across all vertebral regions and exceeded the pre-defined acceptance criteria.

Segmented Part	N	MDC	MDC 95% CI Lower Bound
Individual vertebrae	1193	0.912	0.907
S	38	0.879	0.835
Sacrum (excl. S1)	38	0.901	0.861

- **CT Labeling Accuracy:** The vertebral labeling algorithm demonstrated a mean labeling error of **0.043**.
- **Performance Across Subgroups:** Performance was consistently high across different patient demographics (age, sex) and scan acquisition sources (Europe vs. U.S.A.), demonstrating the model's robustness.

MRI Segmentation Performance Results

The AI model for MRI scans also exceeded the acceptance criteria. The model was validated on lumbar and lower thoracic spine regions.

N	MDC	MDC 95% CI Lower Bound
208	0.903	0.891

5. Summary of Non-Clinical 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. Verification and validation tests demonstrated the subject device is as safe and effective as the predicate device, and performs as intended in the specified use conditions.

- Human Factors and Usability testing was conducted and documentation was provided as recommended in FDA’s guidance document “Applying Human Factors and Usability Engineering to Medical Devices.”
- AI-Enabled Device Performance Validation Report was provided as recommended in FDA’s draft guidance document “Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations.”
- Cybersecurity testing was conducted and documentation was provided as recommended in FDA’s guidance document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.”
- Software verification and validation testing was conducted and documentation provided as recommended in FDA’s guidance document “Content of Premarket Submissions for Device Software Functions.”

6. Substantial Equivalence Conclusion

Based on the information provided in this 510(k) submission, the SpineAR SNAP is substantially equivalent to the predicate device in terms of indications for use, technological characteristics and safety and effectiveness. 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.