Surgical Theater, Inc.
℅ Mr. Kevin Murrock
Sr. Director of Quality and Regulatory
781 Beta Drive
MAYFIELD VILLAGE OH 44143

July 17, 2020

Re: K201465
Trade/Device Name: SuRgical Planner (SRP) BrainStorm
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 2, 2020
Received: June 3, 2020

Dear Mr. 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201465

Device Name
SuRgical Planner (SRP) BrainStorm

Indications for Use *(Describe)*
The SuRgical Planner (SRP) BrainStorm is intended for use as a software interface and image segmentation system for the transfer of image information from a CT, MR, or X-ray 3D Angiography (XA) medical scanner to an output file. It can also be used for pre-operative planning and surgical training in a virtual environment.

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: July 15, 2020

Manufacturer/Submitter:

Surgical Theater, Inc.
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Mayfield Village, Ohio 44143
Phone: (216) 496-7884
Fax: (216) 916-3806

Establishment Registration Number: 3010197287

Contact Person:

Kevin M. Murrock
Sr. Director of Quality and Regulatory
Surgical Theater, Inc.
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Mayfield Village, Ohio 44143
Phone: (330) 472-6520
Email: kmurrock@surgicaltheater.net

Name of Device

- Trade Name: SuRgical Planner (SRP) BrainStorm
- Common Name: System, Image Processing, Radiological
- Classification Name: Picture Archiving and Communications System
- Regulation Number: 21 CFR 892.2050
- Product Code: LLZ
- Regulatory Classification: II
- Device Panel: Radiology

Predicate Device

SuRgical Planner (SRP), 510(k) Number: K170793

Indications for Use:

The SuRgical Planner (SRP) BrainStorm is intended for use as a software interface and image segmentation system for the transfer of image information from a CT, MR, or X-ray 3D Angiography (XA) medical scanner to an output file. It can also be used for pre-operative planning and surgical training in a virtual environment.

The only differences in the Indications for Use statement between the subject device and the predicate are the removal of "Surgical Theater, LLC" and the change from "SuRgical Planner (SRP)" to "SuRgical Planner (SRP) BrainStorm". While the Indications for Use statement of the subject device is not identical to that of the predicate device, these modifications do not alter the intended use nor do they affect the safety and effectiveness of the device.

Device Description:

The SuRgical Planner (SRP) BrainStorm is intended for use as a software interface and image segmentation system for the transfer of image information from a CT, MR, or X-ray 3D Angiography (XA) medical scanner to an output file. It can also be used for pre-operative planning and surgical training in a virtual environment.

The SuRgical Planner (SRP) BrainStorm is not intended to be used for diagnosis.

The SRP BrainStorm software has the ability of creating 3D models of the patient data from 2D scan slices. Additionally, it provides the user with the ability to input, display, color, and manipulate the 2D scan slices via a 3D representation. The software transforms 2D medical images into a dynamic interactive 3D scene with multiple point of views on a high-definition (HD) touch screen monitor. The use of a virtual reality (VR) or augmented reality (AR) headset provides the surgeon a 3D stereoscopic display of the same scene inside the VR / AR headset. While wearing the VR / AR headset, the surgeon can perform a virtual / simulated "fly-through" inside the 3D scene using controllers to perform such actions as rotate, zoom in and zoom out. The use of the SuRgical Planner (SRP) BrainStorm with VR / AR headset and controllers is not intended for use during surgery. The SRP BrainStorm is intended for use for pre-operative planning.

The SRP BrainStorm software includes additional features to facilitate the review of relevant data by a multidisciplinary team that includes neurosurgeons and neurologists for pre-operative surgical planning.

The SRP BrainStorm product does not include 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 design is based on an advanced, touch screen friendly, Graphical User Interface (GUI) that runs an underlying simulation engine to process medical images in DICOM format, and an image generator software engine.

Technological Characteristics

The proposed SRP BrainStorm has similar technological characteristics compared to the predicate device.

The subject and predicate devices are based on the following *same* technological characteristics:

- The ability to create 3D models of the patient data from 2D scan slices. Additionally, it provides the user with the ability to input, display, color, and manipulate the 2D scan slices via a 3D representation. The software transforms 2D medical images into a dynamic interactive 3D scene with multiple point of views on a high-definition (HD) touch screen monitor.
- The use of a virtual reality (VR) headset provides the surgeon a 3D stereoscopic display of the same scene inside the VR headset. While wearing the VR headset, the surgeon can perform a virtual / simulated "fly-through" inside the 3D scene using controllers to perform such actions as rotate, zoom in and zoom out.
- Except for the modifications described below, all other functions are available on both the predicate and proposed devices.

The following modifications were implemented in SRP BrainStorm to provide additional features to be used by a multidisciplinary team that includes neurosurgeons and neurologists for pre-operative surgical planning for neurological disorders:

- Support for augmented reality (AR) headset display and controller to enable the surgeon to experience a 3D stereoscopic view of the same scene displayed on the LED monitor, and also perform actions previously available with a VR headset.
- A simplified planner mode that includes additional features that may be used to facilitate multidisciplinary communication for planning neurosurgery:
    - Tools to detect electrodes from the post electrodes implantation CT and display the results in the 3D scene.
    - Import file containing brain wave recordings that shows the EEG graph output detected during stimulation of each inserted electrode contact.
    - Provide a 360° representation of the locations and intensities of the EEG recordings over time, enabling the team to visually correlate between a physical position of an electrode to the graph readings detected by it in the 3D scene. *No analysis is done on the brain wave recordings, all display and visualization are based on the raw voltage values saved in the imported data file.*

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 SRP BrainStorm is considered substantially equivalent to the predicate SRP in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data

Non-clinical performance testing was performed in support of the substantial equivalence determination. A formal verification and validation plan was executed to confirm that the SRP BrainStorm meets its intended use and performance requirements. In addition, simulated use human factors and usability validation was performed to validate the modifications conform to the user needs and the intended use of the device. Software design verification and validation testing was performed per the same internal design control requirements and methods used for the predicate device.

Verification and validation tests demonstrated the SRP BrainStorm is as safe and effective as the predicate SRP, and performs as intended in the specified use conditions.

Substantial Equivalence Conclusion

Based on the information provided in this 510(k) submission, the SRP BrainStorm is substantially equivalent to the predicate SRP 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.