February 12, 2018

Surgical Theater, LLC
% Mr. Kevin Murrock
Director of Quality and Regulatory
781 Beta Drive
MAYFIELD VILLAGE OH 44143

Re: K170793
Trade/Device Name: SuRgical Planner (SRP)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 6, 2018
Received: February 8, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K170793

Device Name
SuRgical Planner (SRP)

Indications for Use *(Describe)*
The Surgical Theater, LLC SuRgical Planner (SRP) 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.

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

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510(K) SUMMARY
AS REQUIRED BY SECTION 807.92

Purpose of Submission.

Surgical Theater, LLC hereby submits this 510(k) premarket notification to obtain a determination of substantial equivalence for our SuRgical Planner (SRP) software that was formerly known as the Surgery Rehearsal Platform (SRP) (K123023).

510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person and Date Prepared.

Submitter:

Surgical Theater, LLC
781 Beta Drive
Mayfield Village, Ohio 44143
Phone: (216) 496-7884
Fax: (216) 916-3806

Establishment Registration Number: 3010197287

Contact Person:

Kevin M. Murrock
Director of Quality and Regulatory
Surgical Theater, LLC
781 Beta Drive
Mayfield Village, Ohio 44143
Phone: (330) 472-6520
Fax: (216) 916-3806
Email: kmurrock@surgicaltheater.net

Date Prepared: February 9, 2018

Name of Device

- Trade Name: SuRgical Planner (SRP)
- Other Device Trade Names: Surgery Rehearsal Platform, SRP Clinic Viewer
- 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 Theater, LLC Surgery Rehearsal Platform, 510(k) Number: K123023

Device Description:

The SuRgical Planner (SRP) is intended for use as a software interface and image segmentation system for the transfer of imaging 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 is not intended to be used for diagnosis.

The SRP 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) 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. The SRP with VR headset and controllers is not intended for use during surgery. The SRP is intended for use for pre-operative planning.

The SRP 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.

Indications for Use:

The Surgical Theater, LLC SuRgical Planner (SRP) 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 change in the Indications for Use (IFU) of the subject device was due to the addition of the support for X-Ray 3D Angiography (XA) scans. In addition, the phrase "It is also intended as pre-operative software for simulating/evaluating surgical treatment options" was replaced with "It can also be used for pre-operative planning and surgical training in a virtual environment" to clarify that the device is not intended to simulate and evaluate treatment performance and to ensure the device remains under the correct regulation / product code LLZ.

While the Indications for Use statement of the subject device is not identical to that of the predicate device, the device modifications do not alter the intended use of the device nor do they affect the safety and effectiveness of the device or the fundamental scientific technology relative

to the predicate device. Both the subject and predicate devices share the same intended use for pre-operative planning and surgical training in a virtual environment.

Comparison of Technological Characteristics

The primary technological differences between the predicate and modified device are as follows:

1. Added input support for X-Ray 3D Angiography (XA) scans. To be usable by the SRP, the XA scan must be exported by the originating system as a DICOM CT image storage type. During case preparation, the SRP software verifies DICOM data meets the following acceptance criteria; otherwise, data is rejected: 1) Image Modality file type is CT, MR or XA and 2) Media Storage SOP Class and SOP Class UID are CT or MR.
2. The change in the Indications for Use (IFU) of the subject device was due to the addition of the support for X-Ray 3D Angiography (XA) scans as described above in Note 1. In addition, the phrase "It is also intended as pre-operative software for simulating/evaluating surgical treatment options" was replaced with "It can also be used for pre-operative planning and surgical training in a virtual environment" to clarify that the device is not intended to simulate and evaluate treatment performance. While the Indications for Use statement of the subject device is not identical to that of the predicate device, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices share the same intended use for pre-operative planning.
3. The addition of a virtual reality (VR) headset to enable the surgeon to view the scene displayed on the LED monitor in the 3D stereoscopic display of the VR headset.
4. A change in DICOM import library from mDCM to fo-DICOM. The fo-dicom library replaces the obsolete mDCM library and supports all the mDCM library functionalities, as well as adding support for the latest DICOM standard (NEMA PS3.1 - 2006) and future DICOM standard developments.
5. The ability to overlay up to two (2) secondary data sets (i.e. layers) of images over the primary data set of images in the 3D model. This includes tools to align/register images from a secondary data set to the primary data set, and define image segmentation for each secondary layer. Up to five (5) secondary layers may be defined and saved to the case file. The merging of image data sets from different modalities provides additional information to aid surgery planning. For example, CT images are used more often to ascertain differences in tissue density while MR images are typically used to visualize and diagnose tumors.
6. Incorporation of a licensing mechanism consisting of a USB dongle programmed with software features to be enabled, and a software manager that enables or disables features per the programming of the dongle.
7. The ability to launch the FDA cleared (K163324) NNL BrainEx Neuro-Imaging Software for functional MRI installed on the SRP computer from within the SRP application. The

DTI functional images generated from the BrainEx application can then be directly imported into the current case on the SRP.

8. Addition of an SRP Clinic Viewer configuration to be used for patient consultation and surgeon review that will be loaded on either a 1) high-performance touch-screen laptop personal computer or 2) All-in-one high-performance touchscreen desktop PC. The Clinic Viewer configuration provides a limited subset of functions as compared to the SRP desktop configuration. The software functionality is controlled by the USB license dongle and the following general functions are not available: new case preparation, 3D controller, brain atlas, IG lights controls, and VR headset
9. Addition of the Brain Atlas function to provide the ability to superimpose a "generic" brain atlas tissue model directly over the patient-specific 3D model, and provide tools to align and scale the brain atlas model to the patient's 3D model.

Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Electromagnetic Compatibility (EMC)

In order to ensure that the use of the SRP system does not adversely affect other devices within the patient environment, EMC evaluation per IEC 60601-1-2:2007 Third Edition was performed by a 3rd party test laboratory on the modified device and the SRP was found to be in compliance.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "moderate" level of concern.

The SRP was fully tested, verified and validated by Surgical Theater as part of its own internal design control requirements. A formal verification and validation plan was executed to confirm that the modified SRP continues to meet its intended use and performance requirements. The verification and validation report included with this submission summarizes the results of verification and validation activities for the modified device.

Safety and Effectiveness

Product risk management activities were performed in accordance with EN ISO 14971:2012 throughout the product development process. Risk management verification and validation consisted of both a desk audit and software testing to ensure the implementation of all risk mitigations for the device

Conclusions

Modifications to the SRP do not raise new questions of safety and effectiveness.

While the Indications for Use statement of the subject device is not identical to that of the predicate device, the device modifications do not alter the intended use of the device nor do they affect the safety and effectiveness of the device or the fundamental scientific technology relative to the predicate device. Both the subject and predicate devices share the same intended use for pre-operative planning and surgical training in a virtual environment.

Verification and validation results demonstrate the modified SRP is as safe and effective as the predicate SRP, and performs as intended in the specified use conditions.

In summary, the SRP device described in this submission is, in our opinion, substantially equivalent to the predicate device.