DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 28, 2016

Surgical Theater, LLC
% Mr. Kevin M. Murrock
Director of Project Management
781 Beta Drive
MAYFIELD VILLAGE, OH 44143

Re: K160584
Trade/Device Name: Surgical Navigation Advanced Platform (SNAP)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 20, 2016
Received: May 24, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160584

Device Name
Surgical Navigation Advanced Platform (SNAP)

Indications for Use *(Describe)*
The Surgical Theater, LLC SNAP 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 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.

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 modifications to our Surgical Navigation Advanced Platform (SNAP) system (K140819). The modifications are to enhance the surgeon's situational awareness during intra-operative use.

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

Submitter:

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

Establishment Registration Number: 3010197287

Contact Person:

Kevin M. Murrock
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Email: kmurrock@surgicaltheater.net

Date Prepared: May 11, 2016

Name of Device

- Trade Name: Surgical Navigation Advanced Platform (SNAP)
- Other Device Trade Names: VR SNAP & Endo SNAP
- 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 Surgical Navigation Advanced Platform (SNAP), 510(k) Number: K140819

Device Description:

The Surgical Navigation Advanced Platform (SNAP) is intended for use as a software interface and image segmentation system for the transfer of imaging information from CT or MR medical 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.

The Surgical Navigation Advanced Platform (SNAP) transforms medical images into a dynamic, interactive 3D scene, and connects to external 3rd party surgical navigation systems (i.e. "validated systems"), to extract and display intra-operative surgical navigation information (such as the 3D navigation pointer) inside the generated 3D scene. Current navigation systems usually display the navigation data on 2D black and white DICOM imagery within the external navigation system itself. The SNAP displays the same navigation data (pointer position and orientation), as it is received from the external 3rd party navigation system, in a 3D fashion inside the SNAP 3D model of the anatomy as it is reconstructed from the original DICOM slices.

The SNAP allows surgeons to analyze and plan a specific patient's case before surgery, and then take that plan into the operating room (OR) and use it in conjunction with a validated traditional navigation system during surgery. The SNAP then 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. The surgeon can perform a virtual / simulated "fly-through" inside the 3D scene using controls such as rotate, zoom in and zoom out. During pre-operative use a virtual reality (VR) headset 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.

The SNAP 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. 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 SNAP 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 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.

Note: Since the SNAP does not specify a disease, condition, or population (or an anatomical site from which a disease state or population may be inferred), per the FDA Guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] issued on July 28, 2014 it has a general "tool type" indications for use resulting in the intended use and indications for use being the same.

Predicate Device Comparison

The modified SNAP is substantially equivalent to the Surgical Navigation Advanced Platform (SNAP), 510(k) Number: K140819.

Comparative Analysis

Characteristic	Predicate: Surgical Navigation Advanced Platform (SNAP)	Modified: Surgical Navigation Advanced Platform (SNAP)	Explanation of Differences
510(k) Accession Number	K140819	K160584	NA
Clearance Date	June 27, 2014	TBD	NA
Computer	PC Workstation	PC Workstation	NA
Input Data File Format	DICOM	Same	NA
DICOM Image Modality Types Supported	CT and MR	CT, MR and XA	Refer to Note 1 below.

Characteristic	Predicate: Surgical Navigation Advanced Platform (SNAP)	Modified: Surgical Navigation Advanced Platform (SNAP)	Explanation of Differences
Indications for Use	The SNAP is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CT or MR medical 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.	The SNAP 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 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.	Refer to Note 2 below.
Data Transfer Method	CD or USB	Same	NA
Preoperative Planning	Yes	Same	NA
Patient Contact	No	Same	NA
Human Intervention for Interpretation of Images	Yes	Same	NA
Capability of creating 3D models of patient data from 2D scan slices.	Yes	Same	NA
Provides the user with ability to input, display, color, and manipulate the 2D scan slices via a 3D representation.	Yes	Same	NA
Image tools such as rotation, scaling and coloring.	Yes	Same	NA

Characteristic	Predicate: Surgical Navigation Advanced Platform (SNAP)	Modified: Surgical Navigation Advanced Platform (SNAP)	Explanation of Differences
Capability of connecting to an external Surgical Navigation system (e.g. Brainlab Kolibri or Medtronic Stealth), and processing the incoming navigation data.	Yes	Same	NA
Intra-operative Use	Yes	Same	NA
Pre-operative Use	Yes	Same	NA
Multiple Image Merge/Overlay/Alignment	Yes	Same	NA
Software License to Control SNAP Functionality	Yes	Same	NA
Virtual Reality (VR) Headset Display for Pre-Operative Use	No	Yes	**Refer to Note 3 below.**
Virtual Reality (VR) Headset Display for Intra-Operative Use	No	Yes	**Refer to Note 4 below.**
Video Capture PCB to capture video output from a 3rd party endoscopy camera device.	No	Yes	**Refer to Note 5 below.**
Endo View screen presents the live endoscopy video side-by-side with the SNAP 3D scene.	No	Yes	**Refer to Note 6 below.**

Discussion of Differences

The primary 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 SNAP, the XA scan must be exported by the originating system as a DICOM CT image storage type. During case preparation the SNAP 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. X-Ray 3D Angiography (XA) modality support was previously implemented in software release 2.5. The determination that the change could not significantly affect safety or effectiveness and a 510(k) premarket submission was not required was documented in the DHF for software release 2.5. The FDA CDRH guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" was referenced in making this determination.

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. 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 device share the same intended use for simulating and evaluating surgical treatment options both pre-operatively and intra-operatively.
3. The addition of the VR headset to display the 3D scene displayed on the LED monitor in a 3D stereoscopic fashion to increase the user's immersion level in the scene was previously implemented in software release 2.6. The determination that the change could not significantly affect safety or effectiveness and a 510(k) premarket submission was not required was documented in the DHF for software release 2.6. The FDA CDRH guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" was referenced in making this determination.
4. Label the Virtual Reality (VR) Headset Display for Intra-Operative Use. Since the VR headset was not included in the EMC testing of the predicate device, the VR headset was labeled for pre-operative use only. Labeling on the VR headset and in the Operator Manual included the statement "Not Intended for OR Use". The EMC testing for the modified device included the VR headset and since no issues were identified, the VR headset will be available for both pre and intra-operative use with labeling updated accordingly.
5. Add a COTS (commercial off-the-shelf) video capture PCB to the desktop PC to capture live video from any 3rd party endoscopy camera device capable of generating HD video output (e.g. Stryker HD 1188 HD Endoscope Camera System or Storz Image 1 HD Camera Head). The captured endoscopy video presented on the SNAP monitor is identical to the video currently presented on the operating room monitors. An advantage of the SNAP's display is that the endoscopy video is presented side-by-side with the SNAP 3D scenes in the new Endo View screen (refer to item 6 below).
6. Add the Endo View GUI and Screen Layout. Updated GUI and screen layout to simultaneously display the synchronized virtual endoscopy camera and live endoscopy camera device views, the 3D scene showing the endoscope device, and virtual / simulated "fly-through" view to provide the surgeon with an enhanced situational awareness during intra-operative use. The Endo View screen presents the live endoscopy video side-by-side with the SNAP 3D scene.

Performance Data

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

Electromagnetic Compatibility (EMC)

In order to ensure that the use of the SNAP system in the operating room 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 SNAP 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 "medium" level of concern, since a malfunction or latent flaw in the software could delay delivery of appropriate medical care that would likely lead to minor injury.

The SNAP was fully tested, verified and validated by Surgical Theater as part of its own internal design control requirements. A formal verification and validation test plan was executed to confirm that the modified SNAP 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 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 SNAP 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 simulating and evaluating surgical treatment options both pre-operatively and intra-operatively

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

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