Surgical Information Sciences, Inc.
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
PHILADELPHIA, PA 19103

March 31, 2021

Re: K210071
Trade/Device Name: SIS System (Version 5.1.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: January 11, 2021
Received: January 11, 2021

Dear Kelliann Payne:

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: 06/23/2023
See PRA Statement below

510(k) Number *(if known)*
K210071

Device Name

SIS System (version 5.1.0)

Indications for Use *(Describe)*

SIS System is an application intended for use in the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and intraoperative functional planning where the 3D output can be used with stereotactic image guided surgery or other devices for further processing and visualization. The device can be used in conjunction with other clinical methods as an aid in visualization of the subthalamic nuclei (STN) and globus pallidus externa and interna (GPe and GPi, respectively).

Typical users of SIS System are medical professionals, including but not limited to surgeons, neurologists, and radiologists.

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

K210071

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Surgical Information Sciences, Inc.
10405 6th Avenue North, Suite 110
Plymouth, MN 55441
Contact Person: Ann Quinlan-Smith
Phone: 612-325-0187
E-mail: ann.quinlan.smith@surgicalis.com

Date Prepared: March 29, 2021

Trade Name of Device: SIS System version 5.1.0

Common or Usual Name/Classification Name:

Primary: Automated Radiological Image Processing Software (Product Code: QIH; 21 C.F.R 892.2050);
Secondary: System, Image Processing, Radiological (Product Code: LLZ; 21 C.F.R 892.2050)

Regulatory Class: Class II

Predicate Device: Surgical Information Sciences SIS Software version 3.6.0 (K192304)

Intended Use / Indications for Use

SIS System is an application intended for use in the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and intraoperative functional planning where the 3D output can be used with stereotactic image guided surgery or other devices for further processing and visualization. The device can be used in conjunction with other clinical methods as an aid in visualization of the subthalamic nuclei (STN) and globus pallidus externa and interna (GPe and GPi, respectively).

Typical users of SIS System are medical professionals, including but not limited to surgeons, neurologists, and radiologists.

Technological Characteristics

The SIS System version 5.1.0, a software only device based on machine learning and image processing, is designed to enhance standard clinical images for the visualization of structures in the basal ganglia area of the brain, specifically the subthalamic nucleus (STN) and globus pallidus externa and interna (GPe/GPi). The output of the SIS system supplements the information available through standard clinical methods by providing additional, adjunctive information to surgeons, neurologists, and radiologists for use in viewing brain structures for planning stereotactic surgical procedures and planning of lead output.

The SIS System version 5.1.0 provides a patient-specific, 3D anatomical model of specific brain structures based on the patient's own clinical MR image using pre-trained deep learning neural network models. This method incorporates ultra-high resolution 7T (7 Tesla) Magnetic Resonance images to determine ground truth for the training data set to train the deep learning models. These pre-trained deep learning neural network models are then applied to a patient's clinical image to predict the shape and position of the patient's specific brain structures of interest. The SIS System is further able to locate and identify implanted leads, where implanted, visible in post-operative CT images and place them in relation to the brain structure of interest from the preoperative processing.

The proposed device is a modification to the SIS Software version 3.6.0 that was cleared under K192304. The changes made to the SIS System include (1) an updated algorithm that is based on deep learning Convolutional Neural Network models that were architected and optimized for brain image segmentation; (2) the addition of new targets for visualization, specifically the globus pallidus externa and interna (GPe/GPi); and (3) the addition of a functionality to determine the orientation of a directional lead, following its segmentation from the post-operative CT image.

Performance Data

Following the modifications, the software verification and validation testing was repeated to validate that the modified software functions as specified and performs similarly to the predicate device.

To validate the updated algorithm, visualization accuracy testing was conducted for the STN and GPi/GPe structures using the same test methods and acceptance criteria for the previously cleared predicate device. In addition, the company repeated the MRI to CT registration testing to ensure that 3D transformation remains accurate. The company also repeated the testing for image processing

of CT images to validate the lead segmentation. Finally, the electrode orientation detection software was validated on 43 CT image series that contained 55 leads. The software was characterized by two probabilities: the probability of a trusted detection being accurate (within ± 30° of the ground truth) and the probability of an untrusted detection being accurate. When the software trusted the lead detection, it was correct in 91% of cases. This testing demonstrated that greater than 90% of orientations presented to the user are accurate within ± 30°. The results of this testing demonstrated that the SIS System version 5.1.0 has been fully verified and validated and the updated device performs as intended and is as safe and effective compared to the predicate.

Substantial Equivalence

Both the subject and predicate devices are applications intended for use in the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and intraoperative functional planning where the 3D output can be used with stereotactic image guided surgery or other devices for further processing and visualization. Both devices can be used in conjunction with other clinical methods as an aid in visualization of the target brain structures. In addition, typical users of both devices are medical professionals, including, but not limited to surgeons, neurologists and radiologists.

The subject device, like the predicate, operates on other computer platforms and uses a proprietary algorithm to generate 3D segmented anatomical models from patients' MRI scans. The subject device employs an updated version of the algorithm based on deep learning Convolutional Neural Network Models, which were trained to identify the region of interest and individually predict the location and size of the anatomical structures of interest. Furthermore, the addition of the globus pallidus externa and interna (GPe/GPi) structures as well as the functionality to detect the orientation of the implanted directional lead, further facilitate the fundamental clinical purpose for which the predicate was cleared, namely assistance with visualization, surgical planning, image review and analysis. Validation testing demonstrated that the subject device is as safe and effective as the predicate device. The table below provides a summary comparison between the subject and predicate devices.

	SIS System version 5.1.0 (subject device)	SIS Software version 3.6.0 (predicate device)
Intended Use / Indications for Use	SIS System is an application intended for use in the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and intraoperative functional planning where the 3D output can be used with stereotactic image guided surgery or other devices for further processing and visualization. The device can be used in conjunction with other clinical methods as an aid in visualization of the subthalamic nuclei (STN) and globus pallidus externa and interna (GPe and GPi, respectively). Typical users of the SIS System are medical professionals, including but not limited to surgeons, neurologists and radiologists.	SIS Software is an application intended for use in the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and intraoperative functional planning where the 3D output can be used with stereotactic image guided surgery or other devices for further processing and visualization. The device can be used in conjunction with other clinical methods as an aid in visualization of the subthalamic nuclei (STN). Typical users of SIS Software are medical professionals, including but not limited to surgeons, neurologists, and radiologists.
User Population	Medical professionals, including but not limited to surgeons, neurologists and radiologists.	Medical professionals, including but not limited to surgeons, neurologists, and radiologists.
Allows for importing of digital imaging sets	Yes	Yes
Uses proprietary software algorithm to generate 3D segmented anatomical models from patient's MR scans	Yes	Yes

	SIS System version 5.1.0 (subject device)	SIS Software version 3.6.0 (predicate device)
Allows for review and analysis of data in 2D and 3D formats	Yes	Yes
Performs image fusion of datasets using automated or manual image matching technique	Yes	Yes
Segments structures in images with manual and automated tools and converts them into 3D objects for display	Yes	Yes
Creates hybrid datasets by filing in segmented regions slice-by-slice on anatomical datasets	Yes	Yes
Can be downloaded to planning system	Yes	Yes
Segmentation of CT scan to identify structures in relation to those visualized on MR	Yes	Yes
Feature to Account for CT images with gantry tilt	Yes	Yes
Cross-registers images and creates 3D (fused) model	Yes	Yes
Uses registration methods (linear and non-linear) by multiple registration tools (ANTS and ELASTIX)	Yes	Yes

Conclusion

The updated SIS System version 5.1.0 is as safe and effective as the predicate version previously cleared in K192304. The subject device has the same intended use and similar technological characteristics and principles of operation, with minor differences supported by performance validation testing demonstrating that the subject device is as safe and effective as the predicate device. Thus, the minor technological differences between SIS System version 5.1.0 and its predicate device raise no new issues of safety or effectiveness, and the updated SIS System version 5.1.0 is substantially equivalent.