Surgical Information Sciences, Inc.
% Ms. Kelliann Payne
Regulatory Counsel
Hogan Lovells, US LLP
1735 Market Street, Suite 2300
PHILADELPHIA PA 19103

September 13, 2019

Re: K192304
Trade/Device Name: SIS Software Version 3.6.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 23, 2019
Received: August 23, 2019

Dear Ms. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192304

Device Name
SIS Software Version 3.6.0

Indications for Use *(Describe)*

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 the SIS Software 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K192304

510(k) Summary

Sponsor's Name, Contact Information, 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: August 23, 2019

Trade Name of Device: SIS Software version 3.6.0

Common or Usual Name/Classification Name: 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 3.3.0 (K183019)

Intended Use / Indications for Use

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 the SIS Software are medical professionals, including but not limited to surgeons, neurologists and radiologists.

Technological Characteristics

SIS Software uses machine learning and image processing to enhance standard clinical images for the visualization of the subthalamic nucleus ("STN"). The SIS Software supplements the information available through standard clinical methods, providing adjunctive information for use in visualization and planning stereotactic surgical procedures. SIS Software provides a patient-specific, 3D anatomical model of the patient's own brain structures that supplements other clinical information to facilitate visualization in neurosurgical procedures.

The version of the software that is the subject of the current submission (Version 3.6.0) is a modification to the predicate SIS Software version 3.3.0 that was cleared under K183019. The subject and predicate devices rely on the same core technological principles. The only minor changes were modifications to enable the use of a more comprehensive MR to post operation CT registration methodology, and image processing techniques for CT images acquired with gantry

tilt. The web user interface has also been enhanced to allow additional options for administrators/supervisors, and has added audit logging functions.

Substantial Equivalence

The subject and predicate versions of the SIS Software have the same intended use and indications for use. The subject software version, like the predicate, operates on other computing platforms and uses a proprietary algorithm to generate 3D segmented anatomical models from patients' MRI and CT scans. The visualization of the STN is performed in exactly the same way as for the predicate device. While minor modifications to the registration and CT image processing techniques are introduced, the environment of use, role in the clinical workflow, and basis for the device algorithm remain the same, and the core image processing/segmentation principles employed to enable these steps resemble those employed for the MR-based visualization step already cleared. In addition, software validation testing using the same protocol as used for the predicate confirmed that the subject device continues to perform in accordance with its specifications and is as safe and as effective as the predicate.

SIS Software Technological Characteristics Comparison Table

	SIS Software version 3.6.0 (Subject)	**SIS Software version 3.3.0 (Predicate)**
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
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

	SIS Software version 3.6.0 (Subject)	SIS Software version 3.3.0 (Predicate)
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	No
Cross-registers images and creates 3D (fused) model	Yes	Yes
Different registration methods (linear and non-linear) by multiple registration tools (ANTS and ELASTIX)	Yes	No

Performance Data

Following the modifications, the software verification and validation testing has been repeated to validate that the modified software functions as specified and performs similarly to the predicate device. In particular, the company has repeated the MRI to CT registration testing using the new methodology, which demonstrated that the software continued to register MR images to the CT space. The error was within the acceptance criteria, and was comparable to that for SIS Software version 3.3.0, which used the same protocol. In addition, the new image processing for CT images with gantry tilt has been tested to validate objects segmentation. Using the same CT scans that were used in the validation testing for the predicate device, results demonstrated that the cropping image processing does not affect the performance of the software as compared to its predicate.

Conclusions

The updated SIS Software version 3.6.0 is as safe and effective as the predicate version previously cleared in K183019. The subject device has the same intended use and indications for use as the predicate, and very 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 and performs as intended. Thus, the minor technological differences between SIS Software version 3.6.0 and its predicate device raise no new issues of safety or effectiveness, and the updated SIS Software version 3.6.0 is substantially equivalent.