June 14, 2024

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

Re: K241083
Trade/Device Name: SIS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 19, 2024
Received: April 19, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241083

Device Name

SIS System

Indications for Use *(Describe)*

SIS System is 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, visualization and localization. The device can be used in conjunction with other clinical methods as an aid in visualization and location of the subthalamic nuclei (STN), globus pallidus externa and interna (GPe and GPi, respectively) and the ventral intermediate nucleus (Vim) in neurological procedures.

The system is indicated for surgical procedures in which anatomical structure locations are identified in images, including Deep Brain Stimulation Lead Placement.

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.

510(k) SUMMARY

Surgical Information Sciences, Inc.'s SIS System

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

Surgical Information Sciences, Inc.
5201 Eden Avenue, Suite 300
Edina, Minnesota, 55436
Contact Person: Ann Quinlan-Smith
Phone: 612-325-0187
E-mail: ann.quinlan.smith@surgicalis.com

Date Prepared: April 19, 2024

Trade Name of Device: SIS System

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 6.0.0 (K230977)

Intended Use / Indications for Use

SIS System is 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, visualization and localization. The device can be used in conjunction with other clinical methods as an aid in visualization and location of the subthalamic nuclei (STN), globus pallidus externa and interna (GPe and GPi, respectively) and the ventral intermediate nucleus (Vim) in neurological procedures.

The system is indicated for surgical procedures in which anatomical structure locations are identified in images, including Deep Brain Stimulation Lead Placement.

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

Technological Characteristics

The SIS System is a software only device based on machine learning and image processing. The device is designed to enhance standard clinical images for the visualization of structures in the basal ganglia and thalamus areas of the brain, specifically the subthalamic nucleus (STN), globus pallidus externa and interna (GPe/GPi), and ventral intermediate nucleus (Vim). 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 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. The model training method incorporates ultra-high resolution 7T (7 Tesla) Magnetic Resonance (MR) images to determine ground truth for the training dataset, which is comprised of clinical (1.5T and 3T) MR images. 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. 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 System version 6.0.0 that was cleared under K230977. The primary change is the addition of new brain structures to prediction – Vim is now supported based on pre-trained deep learning neural network models.

Performance Data

Software testing was conducted to ensure that the SIS System functions as specified and performs similarly to the predicate device using the same acceptance criteria and the same test designs as used for the previously cleared predicate device.

Visualization accuracy testing was performed to clinically validate the new device feature for visualization of the Vim. A series of images from clinical subjects were collected. Subjects were scanned with both clinical MRI (1.5T or 3T), High Field (7T) MRI and DiMANI (a novel and simple Diffusion MRI datasets method that only depends on the raw signal of the diffusion-weighted volumes) on which the Vim was manually segmented (as ground truth). None of the images from this pivotal validation set were part of the company's database for algorithm development and none were used to optimize or design the SIS's software. This pivotal validation data set was separate from the data set that was used for development. The software development was frozen and labeled before testing on this validation set.

Three measurements were used to compare the SIS visualization via SIS System and ground truth Vim (manually segmented on the DiMANI images): (1) Center of mass distance; (2) Mean surface distance; and (3) Dice coefficient values. For the Vim visualizations, study results showed that 90% of the center of mass distances and mean surface distances were below 1.83mm and 0.86mm, respectively. 95.6% of the center of mass distances and 100% of the surface distances were not greater than 2.00mm. In addition, the mean Dice coefficient in this dataset was 0.7. Thus, the study met the pre-specified criteria of 90% of center of mass distances and surface distances not greater than 2.00mm and average dice coefficient greater or equal to 0.6.

The results of this testing demonstrated that the SIS System has been fully verified and validated to perform as specified, and the subject device is as safe and effective for its intended use as the predicate device.

Substantial Equivalence

In summary, the company's SIS System has the same intended use as the previously cleared SIS System 6.0.0. In addition, the subject SIS System has the same indications and similar technological characteristics, and principles of operation as its predicates. Although there are minor differences between the SIS System and its predicate device, those differences do not raise new or different questions of safety or efficacy. Thus, the SIS System is substantially equivalent.