May 2, 2023

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

Re: K230977
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 5, 2023
Received: April 5, 2023

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,

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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K230977

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) and globus pallidus externa and interna (GPe and GPi, respectively) 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 K230977

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 5, 2023

Trade Name of Device: SIS System

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 Devices

Predicate: Surgical Information Sciences SIS Software version 5.6.0 (K223032)

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) and globus pallidus externa and interna (GPe and GPi, respectively) 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 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 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. As discussed in more detail below, the 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. 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 5.6.0 that was cleared under K223032. The primary changes are the addition of two compatible leads, minor modification to image registration algorithm, and a feature to allow users to view post-operative 3D model in a different coordinate system.

Performance Data

Following the modifications, the software verification and validation testing was conducted to validate that the software 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 repeated to validate visualization of the STN and GPi/GPe structures. 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 using a similar method representative of actual use, and lastly, repeated electrode orientation testing for current lead models and developed a similar method to validate electrode orientation functionality for the new lead models. The company also extended its validation of the head pose for the standardized head position view. The results of this testing demonstrated that the SIS System 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

In summary, the company's SIS System has the same intended use as the previously cleared SIS System 5.6.0. In addition, the 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 questions of safety or efficacy. Thus, the SIS System is substantially equivalent.