DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 14, 2017

Surgical Information Sciences, Inc.
% Ms. Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
PHILADELPHIA PA 19103

Re: K162830
Trade/Device Name: SIS Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 12, 2017
Received: January 12, 2017

Dear Ms. Hogan:

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 on last page

510(k) Number *(if known)*

K162830

Device Name

SIS Software

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.

510(k) SUMMARY

Surgical Information Sciences, Inc.'s SIS Software Device

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

Surgical Information Sciences, Inc.
60 South 6th Street, Suite 2410
Minneapolis, MN 55402
Contact Person: Mark Headrick
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Date Prepared: January 12, 2017

Trade Name of Device

SIS Software

Common or Usual Name / Classification Name

Picture Archiving and Communication System (Product Code: LLZ; 21 C.F.R. 892.2050)

Predicate and Reference Devices

Medtronic's StealthStation (K050438)

Medtronic's Stealth Viz Advanced Planning Application with StealthDTI Package (K081512)

Brainreader ApS' Neuroreader Image Processing Software (K140828) (Reference device)

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 additional, adjunctive information to surgeons, neurologists and radiologists 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 software makes use of the fact that some structures in the brain are not easily visualized in 1.5T or 3T clinical MRI, but are better visualized using high-resolution and high-contrast 7T MRI.

The company's software methodology relies on a reference database of high-resolution brain images (7T MRI) and standard clinical brain images (1.5T or 3T MRI). The 7T images allow visualization of anatomical structures that are then used to find regions of interest within the brain (i.e., the STN) on a patient's clinical image.

SIS visualization is incorporated in the standard clinical MR data, thereby not changing the current standard-of-care workflow protocol and does not require any additional visualization software or hardware platforms.

Performance Data

Developmental testing of the reference database was performed using 10 subject datasets that were retrospectively selected from the locked SIS reference database. For each of the selected datasets, the patient's 7T MRI and labeled structures were excluded from the dataset, such that only the corresponding clinical MRI image remained for the test. The subject machine-learning method then predicted the subthalamic nucleus (STN) on these removed datasets and this prediction was compared to the STN as segmented on the 7T image of that subject to validate the prediction when the tested subject was removed from the dataset (standard leave-one-out statistical procedure). The average distance between the predicted and the original (on the 7T) was 1mm, the actual size of the pixel (data resolution). The overlap between the 3D predicted and the original STN was significantly better ($p<0.05$) in comparison to the overall of a standard atlas and the original STN.

The pivotal validation testing of the subject device, including the reference database, included images from 34 subjects to validate the performance of the SIS Software. A set of 68 STNs (from 34 subjects) were scanned with both clinical MRI (1.5T and 3T) and High Field (7T) MRI. None of the 68 STNs were part of the company's database for algorithm development and none were used to optimize or design the company's software. Thus, this validation data set was completely separate from the data set that was used for development. The software development was frozen and labeled before tested on this validation set.

Three measurements were used to compare the SIS visualization via the subject software and ground truth STNs (manually segmented clinical images and 7T images superimposed): (1) Center of mass distance; (2) Surface distance; and (3) Dice coefficient values.

In sum, 90% of the center of mass distances and surface distances were below 1.9mm and 0.8mm, respectively. Specifically, 95% of the center of mass distances and 100% of the surface distances were not greater than 2.0mm. Thus, the study met the pre-specified criteria of 90% of center of mass distances and surface distances not greater than 2.0mm. Furthermore, the proportion of visualizations not greater than 2.0mm was conservatively estimated from the literature to be 20%. Therefore, the rate of successful visualizations from SIS Software (95% of the center of mass distances not greater than 2.0mm) is significantly greater than the standard of care ($p<0.0001$). The corresponding confidence intervals are as follows:

(a) 90% of the center of mass distances and surface distances were below 1.9mm and 0.8mm, respectively (95% CI: 80.74 – 95.56%);
(b) 95% of the center of mass distances were not greater than 2.0mm (95% CI: 86.91 – 98.37%);
(c) 100% of the surface distances were not greater than 2.0mm (95% CI: 94.25 – 100%).

In addition, the Dice coefficient in this dataset was 0.64, which was expected given the small size of the STN.

In sum, the SIS Software performed as intended and clinical validation data results observed were as expected.

Substantial Equivalence

With regard to technological characteristics, both the SIS Software and the predicates (K050438; K081512) are all software applications that can be used for visualization, presentation and documentation of medical imaging, including different modules for image processing, image fusion, intraoperative functional planning where the 2D or 3D output can be used with stereotactic image guided surgery or other devices for further processing and visualization. In addition, the SIS Software, like the identified predicate and reference devices, use proprietary algorithms to generate 3D segmented anatomical models from patient's MRI scans.

The SIS Software and predicate devices also all perform image fusion of datasets using automated or manual image matching techniques. Below provides a summary comparison between the SIS Software and the predicate and reference devices.

SIS Software Technological Characteristics Comparison Table

	SIS Software	**Medtronic Navigation, Inc.'s Stealth Viz Advanced Planning Application with StealthDTI Package (K081512)**	**Medtronic Navigation, Inc.'s StealthStation (K050438)**	**Braindreader ApS' NeuroReader Medical Image Processing Software (K140828)**
Allows for importing of digital imaging sets	Yes	Yes	Yes	Yes
Uses proprietary software algorithm to generate 3D segmented anatomical models from patient's MR scans	Yes	Yes	Yes	Yes
Allows for review and analysis of data in various 2D and 3D presentation formats	Yes	Yes	Yes	Yes

	SIS Software	Medtronic Navigation, Inc.'s Stealth Viz Advanced Planning Application with StealthDTI Package (K081512)	Medtronic Navigation, Inc.'s StealthStation (K050438)	Braindreader ApS' NeuroReader Medical Image Processing Software (K140828)
Performs image fusion of datasets using automated or manual image matching technique	Yes; atlas-based mapping (patient specific); reference database	Yes; atlas-based mapping	Yes, atlas-based mapping	Yes; reference database
Segments structures in images with manual and automated tools and converts them into 3D objects for display	Yes	Yes	Yes	Yes
Creates hybrid datasets by filing in segmented regions slice-by-slice on anatomical datasets	Yes	Yes	Yes	Yes
Exports results to planning system	Yes	No	Yes	Yes

In sum, the SIS Software has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate and reference devices. The minor technological differences between the subject device and its predicate and reference devices raise no different questions of safety or effectiveness. Performance data demonstrate that the SIS Software performs as intended and is substantially equivalent.