September 17, 2019

Sim&Cure
℅ Scott Blood
Regulatory Consultant
MEDIcept, LLC
22 Nichols Street #2
Salem, Massachusetts 01970

Re: K190049
Trade/Device Name: Sim&Size
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: PZO
Dated: August 2, 2019
Received: August 6, 2019

Dear Scott Blood:

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,

Brian Pullin, M.S
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
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)*
K190049

Device Name
Sim&Size

Indications for Use *(Describe)*
Sim&Size enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. Sim&Size also allows for the ability to computationally model the placement and deployment of neurointerventional devices.
General functionalities are provided such as:
• Segmentation of neurovascular structures
• Automatic centerline detection
• Visualization of X-ray based images for 2D review and 3D reconstruction
• Placing and sizing tools
• Reporting tools
Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

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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Sim&Cure
SECURE YOUR TREATMENT

510(k) Summary

1. Sponsor Name

Submitter's Name: Sim&Cure
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FRANCE
Phone: +33 769 51 37 98

Contact Person: Scott Blood
Regulatory Consultant
MEDIcept
978.729.5978
scottqara@gmail.com

Date of Preparation: September 17, 2019

2. Device Information

Trade Name:	Sim&Size
Common Name:	Radiological Image Processing Software
Regulation Number:	892.2050
Regulation Name:	Picture Archiving and Communications Systems
Class:	II
Product Code:	PZO

3. Predicate Device

K171534 – SurgicalPreview, EndoVantage LLC

4. Device Description

Sim&Size is software that allows for the preoperational planning of medical device sizes for the treatment of intracranial aneurysms. The computational modeling of neurointerventional devices, such as flow diverters and intrasaccular devices, are supported by the software to provide a patient-specific visualization of the deployment of the device from angiographic DICOM data, Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

The Sim&Size software is intended to be loaded on any Windows- or Mac-OS personal computer. A user license(s) must be purchased from the company in order to use the software

after installation. The software also has a training module that offers learning assessments that are relevant to the software.

The software interacts with a patient's DICOM images, the user, and the device. To do so, the graphical interface is organized into three graphical pages (or screens):

a. Patient selection page
b. Module selection page
c. Simulation page

Sim&Size was designed to enable the visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. Sim&Size also allows for the ability to computationally model the placement, deployment and apposition of neurointerventional devices.

5. Intended Use

Sim&Size enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. Sim&Size also allows for the ability to computationally model the placement and deployment of neurointerventional devices.
General functionalities are provided such as:

- Segmentation of neurovascular structures
- Automatic centerline detection
- Visualization of X-ray based images for 2D review and 3D reconstruction
- Placing and sizing tools
- Reporting tools

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

6. Comparison of Technological Characteristics

The predicate device for the Sim&Size software is SurgicalPreview™, cleared per premarket notification K171534. Both Sim&Size and SurgicalPreview have the same indications for use for preoperational planning of neurovascular procedures using existing image data. A summary comparison of technological characteristics in provided below:

Characteristic	**Predicate device** **SurgicalPreview** **K171534**	**Subject device** **Sim&Size** **This submission**
Indications for Use	SurgicalPreview enables visualization and measurement of cerebral blood vessels for preoperational planning and	Sim&Size enables visualization of cerebral blood vessels for preoperational planning and sizing for

Characteristic	**Predicate device** **SurgicalPreview** **K171534**	**Subject device** **Sim&Size** **This submission**
	sizing for neurovascular interventions and surgery. SurgicalPreview also allows for the ability to computationally model the placement and deployment of neurointerventional devices. General functionalities are provided such as: • Segmentation of neurovascular structures • Automatic centerline detection • Visualization of CT scan images for 2D review and 3D reconstruction • Measurement and annotation tools • Reporting tools Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition	neurovascular interventions and surgery. Sim&Size also allows for the ability to computationally model the placement and deployment of neurointerventional devices. General functionalities are provided such as: • Segmentation of neurovascular structures • Automatic centerline detection • Visualization of X-ray based images for 2D review and 3D reconstruction • Placing and sizing tools • Reporting tools Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition
Interface to Image Sources	DICOM Image Data	Same
Import of Patient Data	Manual through keyboard/mouse, automatic import with image file, study creation list	Same
List Image Functionality	Deleting, anonymizing, search	Same
Image Processing	Segmentation by user with clinician review and comment	Same
3D Assessment	Linear (length and diameter) measurements, volume measurements	3D assessment based on 3D model of the simulated device inside the vessels
Image and 3D Display	Orthogonal, color volume rendering, 2D slide review, active presets, 3D view of assemblies of devices	Same
DICOM Support	Compatible with all scanner vendor DICOM datasets, storage SCP, import DICOM files, DICOM compliance for CT and enhanced CT, import from DICOMDIR, storage SCU, query/retrieve SCU	DICOM compliance for CT and enhanced CT, Read DICOM images from 3D rotational angiography stations
Computer OS Compatibility	MS Windows and Mac OS	Same
Data Interchange/Transfer Method	Secure Internet File Server	Transfer by physical media; i.e. USB memory stick

Characteristic	**Predicate device** **SurgicalPreview** **K171534**	**Subject device** **Sim&Size** **This submission**
Output File Format	Web browser via WebGL	Local openGL rendering
Preoperational Planning	Yes	Yes
Patient Contact	No	No
Human Intervention for Interpretation of Images	Yes	Yes

7. Performance Testing

Performance tests on the bench were performed on the Sim&Size. The following were performed**:**

- Tests of importation of DICOM images
- Patient manager tests
- Tests of image display and processing
- Functioning tests for visualization of anatomic reconstruction
- Functioning tests for computational modeling of currently-approved neurovascular devices
- Physical device deployment testing to verify the computational model
- Report creation and visualization tests

All bench testing has been performed and the software has met the required specifications for the completed tests.

9. Summary

Sim&Cure has demonstrated that the Sim&Size is substantially equivalent to its listed predicate device.