December 31, 2020

Sim&Cure
Caroline Oziel
Quality Assurance and Regulatory Affairs Manager
95 rue Pierre Flourens Bâtiment H
Montpellier 34090
France

Re: K202322
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: November 13, 2020
Received: November 25, 2020

Dear Caroline Oziel:

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 Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K202322

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 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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K202322
510(k) Summary

1. Submitter

Submitter's Name: Sim&Cure
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FRANCE
Phone: +33 953 43 88 09

Contact Person: Caroline OZIEL
Quality Assurance and Regulatory Affairs Manager
Sim&Cure

Date of Preparation: December 18, 2020

2. Device Information

Trade Name: Sim&Size
Device Classification Name: Software for Visualization of Vascular Anatomy and Intravascular Devices
Common Name: Radiological Image Processing Software
Regulation Number: 892.2050
Class: II
Product Code: PZO

3. Predicate Device

K190049 - Sim&Size, Sim&Cure.

4. Device Description

The Sim&Size software is a medical device intended to provide a 3D view of the final placement of implants. It uses an image of the patient produced by 3D rotational angiography. It offers clinicians the possibility of computationally model neurovascular implantable medical devices (IMD) in the artery or in the aneurysm to be treated through endovascular surgery, IMD such as the flow-diverters (FD) and the intrasaccular devices (ISD).

Sim&Size is a software designed with two modules. FDsize is the module that allows to pre-operationally plan the choice of size of flow-diverter devices. IDsize is the module that allows to pre-operationally plan the choice of size of intrasaccular devices.
Associated to these two modules, a common module is intended to import DICOM and to provide a 3D reconstruction of the vascular tree in the surgical area.

Sim&Size has been simplified as much as possible to guide the user in an intuitive way in order to reduce the total number of actions required and thus to optimize the time taken to obtain the desired results. There are currently seven steps required to choose the optimal size of an IMD to be placed:

1- Importing the images: the 3D rotational angiography DICOM files are imported.
2- Selecting of the region of interest (ROI): the user positions and focuses a sphere in the placement zone.
3- Threshold validation: the user checks the accuracy of the automatically extracted arterial wall. The threshold can be adjusted if needed.

4- Choosing the entry point: the user clicks on the entry point to the arterial network in order to retrieve the vessel centerlines.
5- Correct automatically or manually the centerline if needed: the user corrects the centerline going through a vessel fusion with the automatic tool or manually.
6- Initializing the implant: the user selects an IMD reference and the ideal placement zone.
7- Sizing the implant: IMD apposition is shown by a color chart in the 3D view. The user can change the IMD reference and placement zone to complete the planning for the intervention.

Patient images can be imported into Sim&Size in two ways: the user has the ability to transfer images using an external storage device (e.g. USB stick) or to retrieve images directly from Scanners Workstation if the option is enabled (only the retrieve function is possible).

The Sim&Size software is compatible with the operating systems MS Windows and Mac OS, when it is first installed a check is done to verify if the user's computer meets the minimum requirements for the use of the software. When a new version of the software is available, the update can be done by the user through a link send by Sim&Cure, the user then follow the instructions indicated in the user manual or by the use of the updater tool SacUpdates that notifies the user, then assists the download and the installation of the last version.

The computational modeling of three devices are supported by the software: Medtronic Pipeline Flex Embolization Device (PED – P100018/S015) flow diverter; Stryker Surpass Evolve Flow Diverter System (Evolve – P170024 S003); and Microvention Woven EndoBridge Aneurysm Embolism System (WEB – P170032) intrasaccular devices. The Medtronic Pipeline Flex Embolization Device, Stryker Surpass Evolve Flow Diverter and Microvention Woven EndoBridge Aneurysm Embolism System devices referenced here are FDA-approved 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 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 with the predicate device

The predicate device for the new version of Sim&Size software is the last version of Sim&Size, cleared per premarket notification K190049. Both versions of Sim&Size have the same indications for use for preoperational planning of neurovascular procedures using existing image data. A summary comparison of technological characteristics is provided below:

Characteristic	**Predicate device Sim&Size version 1.0.5 K190049**	**Subject device Sim&Size version 1.0.6 This submission K202322**
Indications for 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 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.	Same
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	3D assessment based on 3D model of the simulated device inside the vessels	Same
Image and 3D Display	Orthogonal, color volume rendering, 2D slide review, active presets, 3D view of assemblies of devices	Same
DICOM Support	Read DICOM images from 3D rotational angiography stations	Same
Computer OS Compatibility	MS Windows and Mac OS	Same

Characteristic	**Predicate device** **Sim&Size version 1.0.5** **K190049**	**Subject device** **Sim&Size version 1.0.6** **This submission K202322**
Data Interchange/Transfer Method	Transfer by physical media; i.e. USB memory stick	Transfer by physical media; i.e. USB memory stick and Scanner Workstations (retrieve function only).
Output File Format	Local openGL rendering	Same
Preoperational Planning	Yes	Yes
Patient Contact	No	No
Human Intervention for Interpretation of Images	Yes	Yes
Implantable Medical Device (IMD) Database	IMDs included: - Pipeline™ Flex Embolization Device Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, PMA number P100018/S015) - Woven EndoBridge (WEB) Aneurysm Embolization System (MicroVention, Inc., PMA number P170032).	Addition of one IMD database: - Surpass Evolve Flow Diverter System (Stryker Neurovascular, P170024/ S003).
Mechanical solver (used for ID module only)*	Ansys solver (off-the-shelf solver)	Sim&Cure Finite-Element (sacFE) solver (in-house solver)
Fusion correction	Automatic	Automatic and manual

* The FD module doesn't use any mechanical solver but is based on a computational algorithm. No change has been brought to the algorithm on which is based the FDSize module.

7. Performance Data

The following performance data were performed on Sim&Size in support of the substantial equivalence determination.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" in section 16.
The software for this device was considered as a "moderate" level of concern, since prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device.

The performances tested are the following ones:

- Tests of importation of DICOM images.
- Patient manager tests.
- Tests of image display and processing.
- Functioning tests for visualization of anatomic reconstruction.
- Report creation and visualization tests.
- Fusion correction tests (automatic and manual).
- Cybersecurity tests.

The new feature of manual fusion correction has been tested and the tests are passed.
The cybersecurity testing has been improved and all the tests are passed.
In addition, some non-regression testing is included in our continuous tests in order to check if the addition of new features has not involuntarily induced alteration between versions. There is no regression between the predicate device and the version 1.0.6.
All the continuous, supervised and acceptance tests are pass with the version 1.0.6.

All these tests are pass and allow to demonstrate that the performance and the safety are maintained between the predicate device and the device object of this submission.

Performance Testing – Bench
The following performances are tested through the Bench tests : functioning tests for computational modeling of neurovascular devices.

FDsize module

- The verification testing checks that the Flow Diverter final length and apposition computed through the software are conform to their mathematical definition.

- The validation tests are:
  - Experimental benchtests to perform optical acquisitions of new IMD devices samples in both unconstrained and constrained configurations.
  - Realistic in vitro (silicone model) datasets in which the predictability of the simulation model is assessed comparing in-vitro and virtual Flow Diverters devices implanted in silicone phantom of patients presenting with intracranial aneurysms.
  - In vivo studies for which the results are based on comparisons between FD implanted in patients presenting with intracranial aneurysms and virtual FD deployment.

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These validation testing allows to:

- ensure that the simulation model originally implemented is also valid for the new IMD added.
- verify the proper calibration of the simulation model with the device geometrical parameters that were provided by each of the device manufacturers.
- assess the predictability of the product Sim&Size for the new IMDs.

The results obtained in these verification and validation studies allow to demonstrate that the inclusion of the new Implantable Medical Devices databases in the Sim&Size software have no impact on of the safety and performance of the device.

IDsize module

- The verification testing provides the verification and validation of the new in-house mechanical solver. The simulation model is based on this solver, for which a variety of verification test cases were performed. The significant amount of performed verification test cases makes us confident about this in-house solver and enables us to rule on the proper verification of the computational model.

- The validation tests are:
  - Experimental benchtests which assess the accuracy of the IDsize computational model in a well-controlled experimental configuration.
  - Realistic in vitro (silicone model) datasets in which a comparison is done between implanted in silicon phantoms of idealized aneurysms anatomies and virtual WEB computationally modeling with Sim&Size.
  - In vivo studies for which the results are based on comparisons between WEB implanted in patients presenting with intracranial aneurysms and virtual WEB deployment.

These validation testing allows to:

- Demonstrate that the new simulation model appeared to be more robust than the old one and better captures the mechanical behavior of the device when subjected to the compression solicitation than the old simulation model.
- Assess the predictability of the product Sim&Size for the Intrasaccular Device WEB.
- Demonstrate that the new and old model provide a similar overall accuracy.

The results presented in these verification and validation studies allow to demonstrate that integration of the new mechanical solver and the model change in the Sim&Size software have no impact on of the safety and performance of the device.

All performance testing has been performed and passed.
The software Sim&Size in its last version 1.0.6 has met the required specifications for the completed tests.

8. Summary

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