January 27, 2023

Sim&Cure
Colette Maurin
Senior Director, Regulatory Affairs and Quality Assurance
95 rue Pierre Flourens, Bâtiment H
Montpellier, 34090
France

Re: K222664
Trade/Device Name: Sim&Size
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: PZO
Dated: December 28, 2022
Received: December 28, 2022

Dear Colette Maurin:

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
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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)*
K222664

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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K222664
510(k) Summary

1. Submitter

Submitter's Name: Sim&Cure
Address: 95 rue Pierre Flourens, Bâtiment H
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FRANCE
Phone: +33 953 43 88 09

Contact Person: Ms. Colette Maurin
Senior Director, Regulatory Affairs & Quality Assurance

Date of Preparation: January 25th, 2023

2. Device Information

Trade Name: Sim&Size
Device Classification Name: Software for Visualization of Vascular Anatomy and Intravascular Devices
Common Name: Medical image management and processing system
Regulation Number: 892.2050
Class: II
Product Code: PZO

3. Predicate Device

K212373 - Sim&Size, Sim&Cure.

4. Device Description

Sim&Size is a Software as a Medical Device (SaMD) for the simulation of neurovascular implantable medical devices (IMD). The product enables visualization of cerebral blood vessels for preoperational planning for neurovascular interventions and surgery. It uses an image of the patient produced by 3D rotational angiography. It offers clinicians the possibility of computationally modeling the placement of neurovascular IMD in the artery or in the aneurysm to be treated through endovascular surgery and allows to preoperationally plan the sizing and the positioning of IMD.

Sim&Size includes four modules:

- FDsize module allows to pre-operationally plan the choice of size of flow-diverter devices;
- IDsize module allows to pre-operationally plan the choice of size of intrasaccular devices;
- STsize module allows to pre-operationally plan the choice of stents;
- FCsize module allows to pre-operationally plan the choice of first and filling embolization coils.

Associated to these four modules, a common module is intended to import DICOM images and to provide a 3D reconstruction of the vascular tree in the surgical area.

The computational modeling of the following devices is supported by the software:

- In the FDsize module:
  - Medtronic Pipeline Flex Embolization Device (PED – P100018/S015);

- Medtronic Pipeline Flex Embolization Device with Shield Technology (PED2 – P100018/S026);
- Stryker Surpass Evolve Flow Diverter System (P170024/S003);
- MicroVention Flow Re-Direction Endoluminal Device System (FRED – P180027);
- MicroVention Flow Re-Direction Endoluminal Device X System (FRED X – P180027/S002).

• In the IDsize module:
- MicroVention Woven EndoBridge Aneurysm Embolization System (WEB – P170032).

• In the STsize module:
- Stryker Neuroform Atlas Stent System (P180031);
- MicroVention Low-Profile Visualized Intraluminal Support and LVIS Jr (LVIS and LVIS Jr – P170013)

• In the FCsize module:
- Medtronic Axium Detachable Coil and Axium Prime Detachable Coil (K203432);
- MicroVention HydroCoil Embolic System (HES – K161367).

5. Intended Use/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.

6. Indications for Use Comparison

The predicate device for the new version of Sim&Size software is the prior version of Sim&Size, cleared per premarket notification K212373. Both versions of Sim&Size have the same indications for use for preoperational planning of neurovascular procedures using existing image data.

7. Comparison of Technological Characteristics

Compared to the predicate device, which is the prior version of Sim&Size cleared per premarket notification K212373, the new version of Sim&Size subject of this submission includes:

- New FCsize module. This module allows to pre-operationally plan the choice of first and filling coils. The computational modeling of the following embolization coils is supported by the software:

  - Medtronic Axium Detachable Coil and Axium Prime Detachable Coil (K203432);
  - MicroVention HydroCoil Embolic System (HES – K161367).

- Automated region of interest initialization, vessel wall threshold, and vessel entry point features have been added, which should be further verified by the user and can be adjusted, if necessary.

- Ability to computationally model overlapped flow-diverters.

Performance testing and verification and validation activities performed have demonstrated that the device performs as intended. The differences in technological characteristics do not raise new questions of safety and effectiveness of the device.

8. Performance Data

The performance testing of the subject device was developed using the following FDA guidance, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," issued on December 20, 2019.

The performance of computational modeling of neurovascular devices is tested through bench performance testing.

The verification process consists of comparing the behavior of the implantable medical device with its theoretical behavior.

The validation process consists of checking the physical characteristics of the IMD, which are used as input data for the simulation model.

Additionally, a non-clinical study has been performed, in which the predictability of the simulation model is assessed comparing in-vitro and virtual coil devices implanted in silicone phantom based on anatomy of patients presenting with intracranial aneurysms. The tests met the pre-defined acceptance criteria.

Furthermore, two studies using retrospective clinical images have been performed to assess:

- the predictability of the Sim&Size simulations for the Axium (Medtronic) and Hydrogel (MicroVention) embolization coils, comparing the software output (volume embolization ratio) with the measurements taken from retrospective images of previously treated patients.

- the predictability of the Sim&Size simulations for the overlapping flow diverters feature, comparing the software output with the measurements taken from retrospective images of previously treated patients.

9. Summary

Sim&Cure has demonstrated that the Sim&Size software device is substantially equivalent to its listed predicate device. The results of the verification and validation tests demonstrate that the device performs as intended. The inclusion of the new FCsize module in the Sim&Size software and other new features do not raise new questions of safety and effectiveness.