December 14, 2024

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

Re: K242124
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: July 19, 2024
Received: July 19, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael Mcknight -S

for Sara S. Thompson, D.V.M.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242124

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K242124

1 Submitter

Submitter's Name: Sim&Cure
Address: 95 Rue Pierre Flourens, Bâtiment H
34090 Montpellier
FRANCE
Phone: +33 9 53 43 88 09
Contact Person: Ms. Colette Maurin
Senior Director, Regulatory Affairs & Quality Assurance
Date Prepared: December 04th, 2024

2 Device

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

3 Predicate Device

Sim&Size, K222664.
This predicate has not been subject to a recall.

4 Device description

Sim&Size is a Software as a Medical Device (SaMD) for simulating neurovascular implantable medical devices. 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 simulating neurovascular implantable medical devices in the artery or in the aneurysm to be treated through endovascular surgery and provides support in the treatment for the sizing and positioning of implantable medical devices.

Each type of implant device is simulated in a simulation module of Sim&Size:

- FDsize, a module that allows pre-operationally planning Flow-Diverter (FD) devices.
- IDsize, a module that allows pre-operationally planning Intrasaccular (ID) devices.
- STsize, a module that allows pre-operationally planning Stent (ST) devices.
- FCsize, a module that allows pre-operationally planning First and filling coils (FC) devices.

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

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 Comparison of technological characteristics with the predicate device

Sim&Size is a standalone software device that runs on a standard computer. Sim&Size is not intended for use on mobile devices. Sim&Size can use local DICOM files or retrieve them from distant PACS servers. The device does not come into contact with the patient or control any life-support equipment. The 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. In the following comparison table, the devices/functions in bold font are newly added.

Characteristics	**Sim&Size K222664 (Predicate Device)**	**Sim&Size K242124 (Subject Device)**	**Comparison**
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	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	Same

	healthcare provider's judgment and analysis of the patient's condition.	healthcare provider's judgment and analysis of the patient's condition.	
Patient contact	No	No	Same
Human intervention for image interpretation	Yes	Yes	Same
Computer OS Compatibility	MS Windows Mac OS	MS Windows Mac OS	Same
Patient data management	Import: manual through keyboard/mouse, and automatic import with an image file, study creation list. Export Deletion Anonymization Search.	Import: manual through keyboard/mouse, and automatic import with an image file, study creation list. Export Deletion Anonymization Search.	Same
Data interchange	Local files, transfer through physical media (e.g. USB memory stick) and PACS connectivity (query/retrieve)	Local files, transfer through physical media (e.g. USB memory stick) and PACS connectivity (query/retrieve)	Same
DICOM Support	Compatible with DICOM image data from 3D rotational angiography stations.	Compatible with DICOM image data from 3D rotational angiography stations.	Same
Image Processing	Segmentation by user.	Segmentation by user.	Same
Image display	Orthogonal, color volume rendering, active presets, 3D view of assemblies of devices.	Orthogonal, color volume rendering, active presets, 3D view of assemblies of devices.	Same
3D assessment	Assessment based on the 3D model of the simulated implant in the cerebrovascular: - Apposition indication of the implant along the arterial wall/aneurysm wall, - Volume embolization ratio indication of coil (FCsize module), - Metal surface coverage indication of the flow diverter (FDsize module), - Reconstructed structure measurements, - Simulated implant dimensions measurements.	Assessment based on the 3D model of the simulated implant in the cerebrovascular: - Apposition indication of the implant along the arterial wall/aneurysm wall, - Volume embolization ratio indication of coil (FCsize module), - Metal surface coverage indication of the flow diverter (FDsize module), - **Pull-down maneuver of flow diverter deployment in fusiform aneurysms (FDsize module),** - **Compression indication of the implant along the aneurysm wall (IDsize),** - Reconstructed structure measurements, - Simulated implant dimensions measurements.	Similar
Implantable Medical Device Database	In the FDsize module: - Medtronic Pipeline Flex Embolization Device (PED – P100018/S15); - 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 FDsize module: - Medtronic Pipeline Flex Embolization Device (PED – P100018/S15); - Medtronic Pipeline Flex Embolization Device with Shield Technology (PED2 – P100018/S026); **- Medtronic Pipeline Vantage Embolization Device with Shield Technology (PED3 – P100018/S034);** - Stryker Surpass Evolve Flow Diverter System (P170024/S003); **- Stryker Surpass Elite Flow Diverter (P170024/S012);**	Similar

	In the IDsize module: - MicroVention Woven EndoBridge Aneurysm Embolization System (WEB – P170032). In the STsize module: - Stryker Neuroform Atlas Stent System (P180031/S001); - 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);	- 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/S001); - MicroVention Low-Profile Visualized Intraluminal Support and LVIS Jr (LVIS and LVIS Jr – P170013); **- MicroVention Low-Profile Visualized Intraluminal Support EVO (LVIS EVO) (P170013/S004).** In the FCsize module: - Medtronic Axium Detachable Coil and Axium Prime Detachable Coil (K233420); - MicroVention HydroCoil Embolic System (HES – K161367); **- Stryker Target and Target XXL Detachable Coils (K161429);** **- Stryker Target Tetra Detachable Coils (K222533);** **- Balt Optima Coil System (K223386).**	
Results output	Simulation report in PDF and DCM format. Arterial reconstruction with the deployed device in DCM format.	Simulation report in PDF and DCM format. Arterial reconstruction with the deployed device in DCM and **VTP** format.	Similar

7 Performance Data

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Device Software Functions*".

Non-clinical bench performance testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions*".
The testing program comprised the following elements:

- Verification testing, which compares the predictive behavior of the implantable medical device with its theoretical behavior.
- Bench testing, which compares the device placement in a silicone phantom model with the device simulation.

- Retrospective *in vivo* testing, which compares the *in vitro* retrospective cases with the device simulation.

8 Conclusion

The subject and predicate devices are substantially equivalent. The results of the verification and validation tests demonstrate that the Sim&Size device performs as intended. The new features added to the subject device do not raise new questions of safety and effectiveness.