October 25, 2024

SimBioSys, Inc.
Kimberly Oleson
Senior Vice President of Regulatory Affairs
320 N Sangamon, Suite 700
Chicago, Illinois 60607

Re: K243189
Trade/Device Name: TumorSight Viz
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 30, 2024
Received: September 30, 2024

Dear Kimberly Oleson:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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)*
K243189

Device Name
TumorSight Viz

Indications for Use *(Describe)*
TumorSight Viz is intended to be used in the visualization and analysis of breast magnetic resonance imaging (MRI) studies for patients with biopsy proven early-stage or locally advanced breast cancer. TumorSight Viz supports evaluation of dynamic MR data acquired from breast studies during contrast administration. TumorSight Viz performs processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats).

TumorSight Viz also includes user-configurable features for visualizing and analyzing findings in breast MRI studies. Patient management decisions should not be made based solely on the results of TumorSight Viz.

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

K243189

Submitter Details

SimBioSys, Inc.
320 N Sangamon, Suite 700, Chicago IL 60607 United States
Contact: Kimberly Oleson
Contact Telephone: (612) 803-2610
Contact Email: kim.oleson@simbiosys.com
Date of Preparation: September 30, 2024

Details of the Submitted Device

Proprietary Name: TumorSight Viz
Common Name: Medical image management and processing system
Classification Name: System, Image Processing, Radiological
Regulation Number: 892.2050
Product Code: QIH
Committee/Panel: Radiology
Device Class: II

Type of 510(k) Submission:

Special 510(k)

Identification of the Legally Marketed Predicate Device

Predicate #: K231130

Predicate Trade Name: TumorSight Viz

Product Code: QIH

Device Description

TumorSight Viz is an image processing system designed to assist in the visualization and analysis of breast DCE-MRI studies.

TumorSight reads DICOM magnetic resonance images. TumorSight processes and displays the results on the TumorSight web application.

Available features support:

- Visualization (standard image viewing tools, MIPs, and reformats)
- Analysis (registration, subtractions, kinetic curves, parametric image maps, segmentation and 3D volume rendering)
- Communication and storage (DICOM import, retrieval, and study storage)

The TumorSight system consists of proprietary software developed by SimBioSys, Inc. hosted on a cloud-based platform and accessed on an off-the-shelf computer.

Intended Use and Indications for Use

TumorSight Viz is intended to be used in the visualization and analysis of breast magnetic resonance imaging (MRI) studies for patients with biopsy proven early-stage or locally advanced breast cancer. TumorSight Viz supports evaluation of dynamic MR data acquired from breast studies during contrast administration. TumorSight Viz performs processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats).

TumorSight Viz also includes user-configurable features for visualizing and analyzing findings in breast MRI studies. Patient management decisions should not be made based solely on the results of TumorSight Viz.

Indications for Use Comparison

TumorSight Viz has the same Indications for Use as the predicate.

Technological Characteristics

Visualization of dynamic magnetic resonance imaging (MRI) studies is the technological principle for both the subject and predicate devices. It is based on the use of dynamic MRI images in DICOM format which are to be viewed and analyzed by a skilled physician. Both the subject and predicate devices perform the following same technological features:

- Standard Image Viewing Tools (zoom, pan, window/level)
- Image Post Processing (MIPs, reformats, image registration)
- Parametric Maps
- Kinetic Curves
- Automatic Volume Segmentation
- Automatic Linear Measurements (distance to nipple, chest, and closest skin surface)
- DICOM Image Import

The following technological features differ between the subject and predicate devices:

- Automated DICOM image import
- Updated segmentation model

Performance Tests

SimBioSys has completed performance testing on an independent dataset to ensure TumorSight Viz meets clinically acceptable levels.

DCE-MRI were obtained from eight hundred thirty-three (833) patients (corresponding to 916 samples when accounting for bilateral disease) from more than (9) clinical sites in the U.S. for use in training and tuning the device. DCE-MRI were obtained for two hundred sixteen (216) patients (corresponding to 217 samples when accounting for bilateral disease) from more than (7) clinical sites in the U.S. for use in validating the device. All patients had pathologically confirmed invasive, early stage or locally advanced breast cancer.

Data was collected to ensure adequate coverage of MRI manufacturer and field strength, and to ensure similarity with the broader population of early-stage and locally advanced breast cancer patients in the U.S. Specifically, patient age at diagnosis, breast cancer subtype, T stage, N stage, histologic subtype, and race/ethnicity all reflect the broader U.S. population.

	Training Dataset (*n*=676 samples)	**Tuning Dataset (*n*=240 samples)**	**Validation Dataset (*n*=217 samples)**
Age			
<30	22 (3.3%)	3 (1.1%)	6 (2.8%)
30-39	121 (17.9%)	36 (13.6%)	32 (14.7%)
40-49	202 (29.9%)	68 (25.8%)	51 (23.5%)
50-59	216 (32.0%)	69 (26.1%)	71 (32.7%)
60-69	94 (13.9%)	43 (16.3%)	44 (20.3%)
>70	21 (3.1%)	21 (8.0%)	13 (6.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Race/Ethnicity			
Black†	69 (10.2%)	54 (20.5%)	26 (12.0%)
Asian and Pacific Islander†	31 (4.6%)	8 (3.0%)	21 (9.7%)
White†	471 (69.7%)	167 (63.3%)	150 (69.1%)
American Indian or Alaska Native†	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	9 (1.3%)	3 (1.1%)	4 (1.8%)
Hispanic	0 (0.0%	6 (2.3%)	10 (4.6%)
Missing/Unknown	96 (14.2%)	2 (0.8%)	6 (2.8%)

† Non-Hispanic

The following subgroups present in the dataset were comparable to the U.S. population: cancer subtype, grade, histology, T stage, and N stage.

Images were acquired from sites that utilize standard of care dynamic contrast enhanced MR protocols from GE, Philips, and Siemens scanners with both 1.5T and 3T field strength magnets.

Three (3) U.S. Board Certified radiologists reviewed 217 validation samples to establish the ground truth for the dataset according to predefined guidelines. For each case, two radiologists measured various characteristics about the cancer including longest dimensions along three axes and tumor to landmark (chest, nipple, skin) distances. Each study was reviewed by two radiologists to determine if the candidate segmentation was appropriate. In cases where the two radiologists did not agree on whether the segmentation was appropriate, a third radiologist provided an additional opinion and established a ground truth by majority consensus.

Independence of validation data from training data was ensured by confirming there was no overlap of patients between training/tuning and validation datasets.

The validation samples were tested using both TumorSight Viz and the predicate device.

The measurements generated from the device result directly from the segmentation methodology and are an inferred reflection of the performance of the deep learning algorithm. For example, the distance from chest or skin is calculated after the deep learning segmentation identifies the region of interest and then the resulting measurement is output.

The mean absolute error and variability between the automated measurements (Validation Testing) and ground truth for tumor volume (measured in cc) and landmark distances (measured in cm) was similar to the variability between device-to-radiologist measurements and inter-radiologist variability. This demonstrates that the error in measurements is consistent to the variability between expert readers. Performance data for the automated measurements is summarized below:

Measurement Description	**Units**	**Validation Testing (Mean Abs. Error ± Std. Dev.)**
Tumor Volume (n=184)	cubic centimeters (cc)	5.22 ± 15.58
Tumor-to-breast volume ratio (n=184)	%	0.51 ± 1.48
Tumor longest dimension (n=202)	centimeters (cm)	1.60 ± 1.93
Tumor-to-nipple distance (n=200)	centimeters (cm)	1.20 ± 1.37
Tumor-to-skin distance (n=202)	centimeters (cm)	0.63 ± 0.61
Tumor-to-chest distance (n=202)	centimeters (cm)	0.91 ± 1.14
Tumor center of mass (n=184)	centimeters (cm)	0.72 ± 1.42

The tumor segmentation was assessed using the Dice coefficient, utilizing both the volumetric and surface Dice coefficients, which together validate the location, volume, and surface agreement with a reference standard.

The surface Dice coefficient is particularly useful as a proxy for the accuracy of 3D rendering and surface-to-surface distances. Additionally, to further assess the tumor segmentation localization accuracy, we used the distance between the centers of mass of the reference standards and device-generated regions.

Results of Dice and surface Dice are summarized below:

Performance Measurement	**Metric**	**Validation Testing (Mean ± Std. Dev.)**
Tumor segmentation (n=184)	Volumetric Dice	0.75 ± 0.24
	Surface Dice	0.88 ± 0.24

We found that all tests met the acceptance criteria, demonstrating adequate performance for our intended use.

Risk Management

The device risks were managed and controlled following the requirements of ISO 14971 standard. The device hazards were identified, their risk levels were evaluated and mitigation measures were taken to reduce the risk levels. The benefits of the TumorSight Viz software, outweigh the device residual risks.

Substantial Equivalence

TumorSight Viz is comparable to the predicate in terms of intended use, technological characteristics, and principle of operation.

A table comparing the key features of the subject and predicate devices is provided below:

Predicate Device Comparison		
	Predicate Device	**TumorSight Viz**
510(k)	K231130	K243189
Manufacturer	SimBioSys, Inc.	SimBioSys, Inc.
Regulation Number	892.2050	892.2050
Regulation Name	Medical image management and processing system	Medical image management and processing system
Classification	2	2
Device Common Name	Image Processing System	Image Processing System
Product Code	QIH	QIH
Functions	- Extract dynamic contrast enhanced MRI sequence from MRI images for the 3D display and visualization of the anatomy of patient's breast	- Extract dynamic contrast enhanced MRI sequence from MRI images for the 3D display and visualization of the anatomy of patient's breast

Intended Use	TumorSight Viz is intended to be used in the visualization and analysis of breast magnetic resonance imaging (MRI) studies for patients with biopsy proven early-stage or locally advanced breast cancer. TumorSight Viz supports evaluation of dynamic MR data acquired from breast studies during contrast administration. TumorSight Viz performs processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats). TumorSight Viz also includes user-configurable features for visualizing and analyzing findings in breast MRI studies. Patient management decisions should not be made based solely on the results of TumorSight Viz.	TumorSight Viz is intended to be used in the visualization and analysis of breast magnetic resonance imaging (MRI) studies for patients with biopsy proven early-stage or locally advanced breast cancer. TumorSight Viz supports evaluation of dynamic MR data acquired from breast studies during contrast administration. TumorSight Viz performs processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats). TumorSight Viz also includes user-configurable features for visualizing and analyzing findings in breast MRI studies. Patient management decisions should not be made based solely on the results of TumorSight Viz.
Data Source (Input)	MRI	MRI
Output/Accessibility	Graphic and text results of breast anatomy are accessed via a device with internet connectivity	Graphic and text results of breast anatomy are accessed via a device with internet connectivity
Physical Characteristics	"-non-invasive software package -DICOM compatible"	"-non-invasive software package -DICOM compatible"
Safety	Clinician review and assessment of analysis prior to use in pre-operative planning.	Clinician review and assessment of analysis prior to use in pre-operative planning.

Predicate Device Feature Comparison		
Feature	Predicate Device	TumorSight Viz
Standard image viewing tools	Yes	Yes
MIPs	Yes	Yes
Reformats	Yes	Yes
Registration	Yes	Yes
Subtraction series	Yes	Yes
View 3D volume rendering	Yes	Yes
Kinetic curves	Yes	Yes
Parametric image maps	Yes	Yes
Manual DICOM import	Yes	Yes
Automated DICOM image import	No	Yes
Updated segmentation model	No	Yes
View finding volume	Yes	Yes
View finding location	Yes	Yes
View finding size	Yes	Yes
View kinetic curve with highest uptake	Yes	Yes
View finding distance to nipple	Yes	Yes
View finding distance to skin	Yes	Yes
View finding distance to chest	Yes	Yes
View adjusted finding size	No - Segmentation is not editable, but surgical margins are editable	No - Segmentation is not editable, but surgical margins are editable
Interactive rotation of 3D volume rendering	Yes	Yes

Performance of TumorSight Viz was directly compared to that of the predicate for measurements including tumor longest dimension, tumor to skin distance, tumor to chest distance, and tumor to nipple distance. As summarized in the following table, these were comparable to inter-radiologist variability in the same measurements:

Performance Measurement	N	Metric	Predicate/ TumorSight Viz	TumorSight Viz/ Ground Truth	Predicate/ Ground Truth	Inter-radiologist Variability
			(Mean ± Std. Dev.)	(Mean ± Std. Dev.)	(Mean ± Std. Dev.)	(Mean ± Std. Dev.)
Longest Dimension	197	Abs. Distance Error	1.33 cm ± 1.80 cm	1.59 cm ± 1.93 cm	1.27 cm ± 1.34 cm	1.30 cm ± 1.34 cm
Tumor to Skin	197	Abs. Distance Error	0.24 cm ± 0.39 cm	0.61 cm ± 0.60 cm	0.55 cm ± 0.48 cm	0.51 cm ± 0.48 cm
Tumor to Chest	197	Abs. Distance Error	0.64 cm ± 1.13 cm	0.89 cm ± 1.12 cm	0.69 cm ± 0.88 cm	0.97 cm ± 1.16 cm
Tumor to Nipple	195	Abs. Distance Error	0.89 cm ± 1.03 cm	1.15 cm ± 1.30 cm	1.01 cm ± 1.23 cm	1.03 cm ± 1.30 cm
Tumor Volume	197	Abs. Volume Error	4.42 cc ± 11.03 cc	5.22 cc ± 15.58 cc	6.50 cc ± 21.40 cc	NA

The differences in error between the mean absolute errors (MAE) for the predicate and subject device are clinically acceptable because they are on the order of one to two voxels for the mean voxel size in the dataset. These differences are clinically insignificant.

Substantial Equivalence Conclusion

The comparison of the features and non-clinical bench performance testing described above demonstrates that TumorSight Viz is substantially equivalent to the predicate device in function. Furthermore, performance testing in an independent dataset of radiologist measurement ground truth demonstrates adequate performance for the intended use.

Additionally, TumorSight Viz measurement outputs were compared directly to the predicate device output for 197 cases, and both sets of measurements were directly compared to radiologist measurements. TumorSight Viz compared equivalently to the predicate device on all measurements including tumor longest dimension, tumor to skin distance, tumor to chest distance, and tumor to nipple distance.

Non-clinical bench testing, an independent assessment of device performance to radiologist ground truth, and a direct comparison to the predicate device demonstrate that TumorSight Viz is substantially equivalent to the predicate device.

Functions Not Subject to FDA Premarket Review

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.