



September 25, 2026

SimBioSys, Inc.
% John Smith
Partner
Hogan Lovells US LLP
555 13th St., NW
Washington, District of Columbia 20004

Re: K260023

Trade/Device Name: TumorSight Risk
Regulation Number: 21 CFR 864.3755
Regulation Name: Software algorithm device analyzing digital images for cancer prognosis
Regulatory Class: Class II
Product Code: SHW
Dated: January 5, 2026
Received: January 5, 2026

Dear John Smith:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 and Part 809); 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 Management System Regulation (QMSR) (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,

SHYAM KALAVAR -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K260023

Device Name

TumorSight Risk

Indications for Use (Describe)

TumorSight Risk is an artificial intelligence based software only device that analyzes data from previously diagnosed invasive breast cancer patients to assess the risk of recurrence. TumorSight Risk utilizes the following data: age, race, cancer stage, nodal status, and grade, combined with Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI) data to generate 5- and 10-year risks of breast cancer recurrence and a proprietary prognostic score.

TumorSight Risk is intended for use in adult women with hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-), lymph node negative (N0) or positive (N1), Stage I-III breast cancer to inform a physician in prognostic risk-based decisions in conjunction with other relevant clinicopathological factors.

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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TumorSight Risk 510(k) Summary

Submission Number: K260023

Submitter Details

SimBioSys, Inc.
320 N Sangamon St, Suite 700, Chicago IL 60607 United States
Contact: Joseph R. Peterson
Contact Telephone: +1 (217) 903-3865
Contact Email: jrp@simbiosys.com
Date of Preparation: September 24, 2026

Details of the Submitted Device

Proprietary Name: TumorSight Risk
Common Name: Software algorithm device analyzing digital images for cancer prognosis
Regulation Number: 21 CFR §864.3755
Product Code: SHW
Committee/Panel: Pathology
Device Class: II

Identification of the Legally Marketed Predicate Device

Predicate: K254115
Predicate Trade Name: ArteraAI Breast
Regulation Number: 21 CFR §864.3755
Product Code: SHW
Committee/Panel: Pathology

Intended Use and Indications for Use

TumorSight Risk is an artificial intelligence based software only device that analyzes data from previously diagnosed invasive breast cancer patients to assess the risk of recurrence. TumorSight Risk utilizes the following data: age, race, cancer stage, nodal status, and grade, combined with Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI) data to generate 5- and 10-year risks of breast cancer recurrence and a proprietary prognostic score.

TumorSight Risk is intended for use in adult women with hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-), lymph node negative (N0) or positive (N1), Stage I-IIIa breast cancer to inform a physician in prognostic risk-based decisions in conjunction with other relevant clinicopathological factors.

Device Description

TumorSight Risk employs artificial intelligence (AI) algorithms and image processing to analyze data from previously diagnosed invasive breast cancer patients. TumorSight Risk integrates standard-of-care diagnostic pathology data with clinical and medical imaging data to provide a proprietary prognostic TSR score ranging from 0-100 that is used to determine a risk category and prognostic risk estimate of recurrence of the disease within 5 years and 10 years from diagnosis.

The below table shows the TSR score range and the associated risk category.

TumorSight Risk 510(k) Summary

TSR Score Range	TumorSight Risk Category
>35	High
>20 to ≤35	Intermediate
≤20	Low

TumorSight Risk utilizes the TumorSight Platform for system access and system cybersecurity.

TumorSight Risk is intended to be used with the following MRI manufacturer/field strength: General Electric (GE) 1.5T, GE 3T, Siemens 1.5T, Siemens 3T.

Device Input:

1. Age, race, clinical tumor (T) stage, clinical nodal (N) stage, tumor histologic grade
2. Multi-tissue segmentation map which is derived from processing the patient's pre-treatment dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) acquired according to American College of Radiology (ACR) guidelines. This input is a validated output of the TumorSight Viz device (K251766)

Additional patient required information by the software, but are not inputs to the device. These include ER/PR/HER2 status, which is used by the software to determine case eligibility criteria per indications for use. They are not used by the AI algorithm for device output generation (Risk Category or TSR Score). Additionally, cancer laterality information is used to ensure that the appropriate multi-tissue segmentation map is retrieved from TumorSight Viz. It is a processing input used to associate the DCE MRI images with the correct segmentation output, rather than an input feature of the TumorSight Risk AI model itself. Patient clinical data, i.e., age, race, clinical T stage, clinical N stage, tumor histologic grade, and multi-tissue segmentation map obtained from DCE-MRI are utilized by the TumorSight Risk AI algorithm to compute the device output (TumorSight Risk (TSR) Score and Risk Category).

A summary of the device operation is as follows:

1. DCE MRI data (e.g., in DICOM format) is input into the previously cleared TumorSight Viz device. TumorSight Viz processes the data and generates a multi-tissue segmentation.
2. The multi-tissue segmentation is automatically input into TumorSight Risk from the TumorSight Viz device.
3. Intermediate imaging values are computed from the multi-tissue segmentation.
4. The intermediate imaging values are combined with clinical and pathologic data and input into a machine learning algorithm that generates a proprietary TSR Score and risk category ("High Risk", "Intermediate Risk", or "Low Risk").

Device Output:

1. Proprietary TSR Score ranging from 0-100 that is used to determine a risk category
2. Categorical assessment of "High Risk", "Intermediate Risk" or "Low Risk"
3. Observed 5-Year Risk of recurrence (in the clinical validation dataset)
4. Observed 10-Year Risk of recurrence (in the clinical validation dataset)

This output is displayed in a report format ("Risk Report") which describes the TumorSight Risk methodology and summarizes validation results.

TumorSight Risk 510(k) Summary

Algorithm Development

The TumorSight Risk algorithm is a regression-based machine learning model that integrates clinical, demographic, pathologic and imaging features. The model was trained/tuned using a dataset of N=1,133 samples from 6 sites geographically distributed throughout the US. The development (training plus tuning) dataset was representative of the US population (see Table 1). The training portion of the development dataset was used to generate candidate models, while the tuning portion of the development dataset was used to select the final model. The candidate model was tested for repeatability, reproducibility, accuracy, and stability. the algorithm was locked after model training and prior to analytical precision testing and clinical validation.

Table 1: Demographics of US Population along with the training/tuning dataset. Patient demographics in the training/tuning dataset demonstrate that the algorithm was developed on a population that is representative of the intended use population. Dataset has representation across age, race, cancer subtype, histology, grade, T stage and N stage.

Factor	US Population (%)	Training/Tuning N=1,133 (%)
Institution		
Site 1	-	159 (14.0%)
Site 2	-	397 (35.0%)
Site 3	-	102 (9.0%)
Site 4	-	48 (4.2%)
Site 5	-	20 (1.8%)
Site 6	-	407 (35.9%)
Age*		
22-29	<1%	8 (<1%)
30-39	4%	91 (8%)
40-49	13%	307 (27%)
50-59	22%	343 (30%)
60-69	29%	238 (21%)
70-79	21%	124 (11%)
80+	11%	20 (2%)
Unknown	-	2 (<1%)
Race**		
White	71%	844 (75%)
Black or African American	12%	204 (18%)
Asian	5%	21 (2%)
Native Hawaiian or Other Pacific Islander†	<1%	0 (0%)
American Indian or Alaska Native†	1%	5 (<1%)
Other†	10%	50 (4%)
Unknown†	-	9 (<1%)
Cancer Grade*		
1	21%	242 (21%)
2	42%	606 (54%)
3	29%	255 (22%)
Unknown	8%	30 (3%)
Clinical Tumor Stage***		

TumorSight Risk 510(k) Summary

T1	55%	537 (47%)
T2	31%	404 (36%)
T3	8%	138 (12%)
T4	1%	1 (<1%)
Unknown	6%	53 (5%)
Clinical Nodal Stage***		
N0	66%	752 (66%)
N1	25%	277 (24%)
N2	6%	0 (0%)
N3	0%	0 (0%)
Unknown	3%	104 (9%)
Breast Laterality†		
Left	50.8%	577 (50.9%)
Right	49.2%	556 (49.1%)
Recurrence (Any Time)		
True	-	144 (12.7%)
False	-	989 (87.3%)

Table Footnote:

* US population age and grade statistics are from: Gianquinto, AN, Hyuna Sung, Kimberly D. Miller, et al. Breast Cancer Statistics, 2022. *CA: A Canc J for Clins.*, 2022; 72(6):524-541. doi:10.3322/caac.21754

** US population race statistics from: U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; <https://www.cdc.gov/cancer/dataviz>, released in June 2025.

*** US population Tumor and Nodal stage statistics from: American Cancer Society. *Breast Cancer Facts & Figures 2024-2025*. Atlanta: American Cancer Society; 2024.

† Within the TumorSight Risk device and algorithm, races other than White and Black are categorized as “Other”.

‡ Laterality statistics are from: Abdou, Y., Gupta, M., Asaoka, M. et al. Left sided breast cancer is associated with aggressive biology and worse outcomes than right sided breast cancer. *Sci Rep* 12, 13377 (2022)

Technological Characteristics

TumorSight Risk is a software algorithm device analyzing digital images for breast cancer prognosis. This prescription device analyzes acquired DCE-MRI and clinicopathologic input data to provide prognostic risk estimates for breast cancer patients with previously diagnosed cancer. The software medical device utilizes output of the cleared TumorSight Viz device along with AI/ML algorithms to generate an estimate for the risk of recurrence at 5 years and 10 years. The predicate device is also a software algorithm device analyzing digital images for breast cancer prognosis.

Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility

A study using simulated noise added to MRIs was conducted to assess the precision/reproducibility of the TumorSight Risk algorithm. One hundred twenty (120) patient images were selected which were evenly split across GE/1.5T, GE/3T, Siemens/1.5T, Siemens/3T MRI manufacturer/field strength combinations. These images were processed through the system three times with 3% added Rician noise. N=119/120 successfully processed. Summary precision statistics for: i) the variability of SD standard deviation (SD)

TumorSight Risk 510(k) Summary

(mean values of SD, the median of SD); ii) the variability of percent coefficient of variation (%CV) ((mean values of %CV, the median of %CV)), and iii) the percent agreement are shown in Table 2 below. Precision profiles are shown in Figure 1 below.

Table 2. Summary precision results for the (n=119) for the TSR Score.

Factor	Overall (N=119)	GE/1.5T (N=30)	GE/3T (N=30)	Siemens/1.5T (N=30)	Siemens/3T (N=29)
SD (mean, median)	0.23 (0.12)	0.25 (0.09)	0.21 (0.11)	0.21 (0.17)	0.25 (0.12)
%CV (mean, median)	0.61 (0.31)	0.48 (0.25)	0.44 (0.26)	0.51 (0.36)	1.06 (0.33)
%Agreement (N*3 replicates)	99.4% (355/357)	98.9% (89/90)	100% (90/90)	98.9% (89/90)	100% (87/87)
%Disagreement (N*3 replicates)	0.6% (2/357)	1.1% (1/90)	0% (0/90)	1.1% (1/90)	0% (0/87)

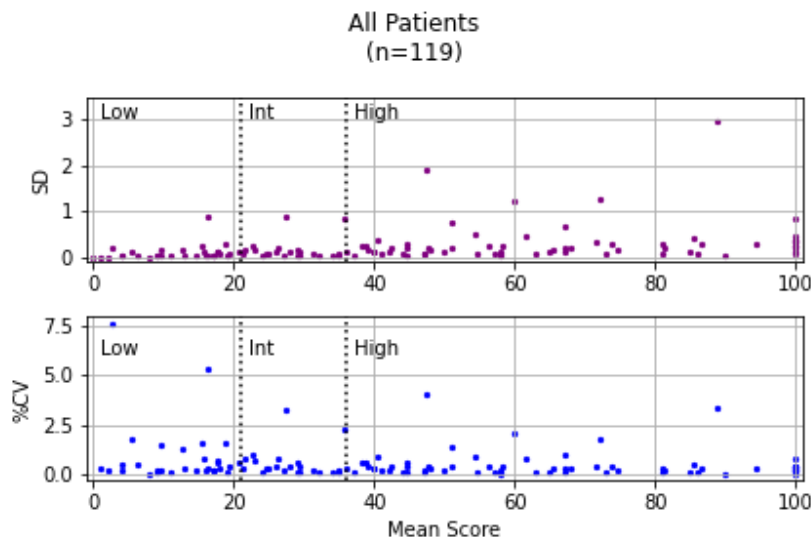


Figure 1: Precision profiles for all N=119 subjects included in the study for the TSR Score.

2. Human Factors Study

Human Factors Validation Testing confirmed that TumorSight Risk can be used safely and effectively by its intended users in real-world conditions. Thirty (30) participants (physicians and clinical support staff) successfully completed all critical tasks with no safety concerns, validating that training and mitigations were effective.

3. Clinical Studies

The clinical performance of TumorSight Risk was evaluated in a retrospective clinical study which included a total of 2,129 patients across 4 sites in the US. Enrollment included identification of patients that were diagnosed between January 1, 2010, and December 31, 2024, and had a pre-treatment MRI available. The clinical, pathologic and recurrence data elements were extracted from the medical record and/or cancer registry.

The measures of the clinical performance for the device with three outputs (High, Intermediate, Low)

TumorSight Risk 510(k) Summary

are i) Predictive Value (PV) for each output and ii) percentage of the results for each output. Predictive Values are evaluated using Kaplan-Meier analyses, from the “High”, “Intermediate” and “Low” populations, respectively.

The study analyzed risk in N=2,129 cases. Input data to the device, including DCE-MRI and clinicopathologic factors, were collected from the sites and processed through the TumorSight Risk device. Recurrence information for patients was also collected from the sites and stored in a sequestered locked database. All cases were successfully processed, producing risk scores and risk classifications. After the device was run and the outputs locked, the recurrence information was unlocked and the study endpoints assessed per the study protocol.

a. Clinical positive predictive value (PPV)

PPV is the probability that an event occurs within a specific time frame given the device output for that patient is high risk.

PPV(5 years) = 9.8% (95%CI: 7.4%-12.9%)

PPV(10 years) = 26.4% (95%CI: 20.2%-34.1%)

b. Clinical negative predictive value (NPV)

NPV is the probability that an event does not occur within a specific time frame given the device output for that patient is low risk.

NPV(5 years) = 97.0% (95%CI: 95.7%-98.0%)

NPV(10 years) = 91.4% (95%CI: 88.5%-93.6%)

c. Risk of Recurrence by Risk Category

Estimates for the risk of recurrence by TumorSight Risk Category in the clinical validation population are shown in the following table:

Table 3: Estimates for the risk of recurrence by TumorSight Risk Category in the clinical validation population

Risk Category	Risk of Recurrence Estimate at 5 years (95% CI)	Risk of Recurrence Estimate at 10 years (95% CI)
Low Risk	3.0% (2.0%, 4.3%)	8.6% (6.4%, 11.5%)
Intermediate Risk	5.7% (4.0%, 8.2%)	13.4% (9.6%, 18.5%)
High Risk	9.8% (7.4%, 12.9%)	26.4% (20.2%, 34.1%)

d. Other clinical supportive data

i. Risk Estimation

The following chart shows the Cumulative Probability of Recurrence curves of the low, intermediate and high risk patients along with all subjects in the study population through 10 years:

TumorSight Risk 510(k) Summary

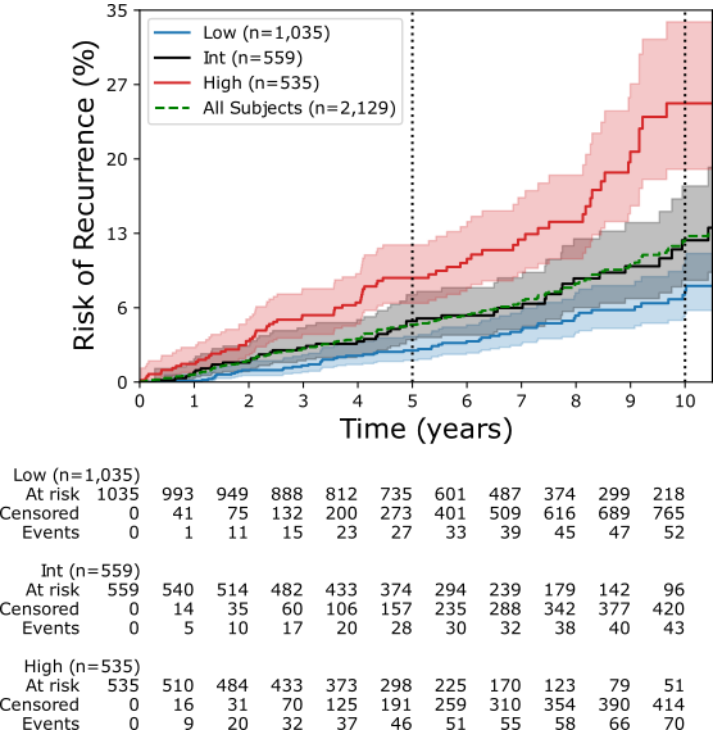


Figure 2: Cumulative Probability of Recurrence Curves of the Study Population. Recurrence curves for the high-, intermediate (int) and low-risk fractions of the whole study population (N=2,129) are shown. The vertical lines delineate the 5-year and 10-year analysis endpoints.

- ii. Results Distribution
- Patients in the study, while having TSR scores across the range of risk scores, were not evenly distributed. Patient data was binned into the 0-25th, 25th-50th, 50th-75th, 75th-90th, and 90th-100th percentiles of score distribution. The recurrence rate and 95% confidence intervals at 5- and 10-years were estimated from the clinical study data and plotted against TSR Score.

TumorSight Risk 510(k) Summary

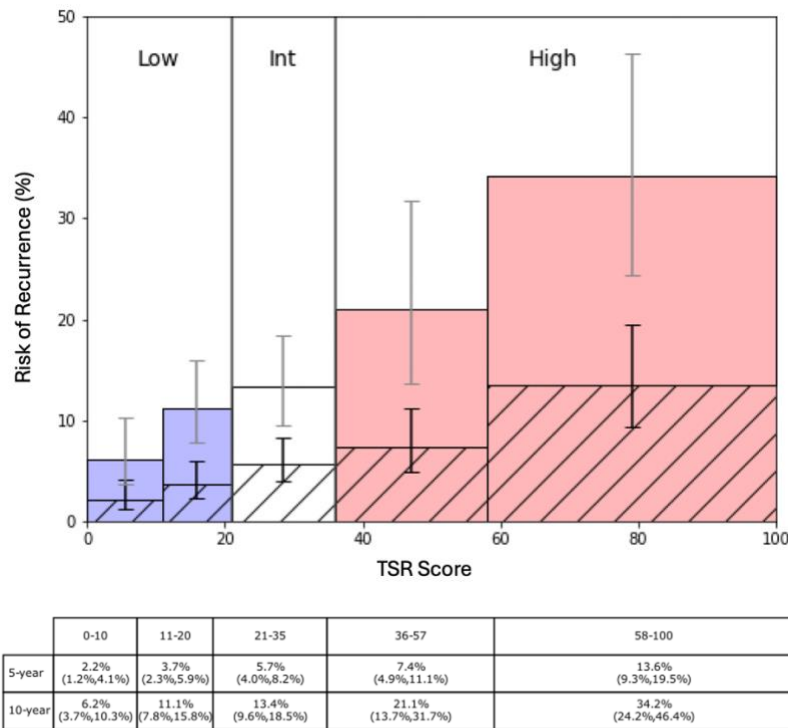


Figure 3: Clinical Validation Study Data showing Risk of Recurrence (%) vs. TSR Score. The empirically determined recurrence probability at 5-year and 10-years is plotted on the y-axis along with 95% CIs, versus TSR score on the x-axis. Hatched boxes and black error bars show 5-year recurrence probability. Open boxes and grey error bars show 10-year recurrence probability.

Table 4: Empirically Determined Recurrence Probability versus TSR Score.

Risk Category	Device output (TSRS Range)	Device Output (Mean TSRS)	Sub-Interval	N (patients)	TSRS Range	Observed Recurrence Rate at 5 years (95% CI)	Observed Recurrence Rate at 10 years (95% CI)	Percentage of patients in the bin
Low	[0, 11)	5.2	1	515	[0, 10]	2.2% (1.2%, 4.1%)	6.2% (3.7%, 10.3%)	24.2%
Low	[11, 21)	15.0	2	521	[11, 20]	3.7% (2.3%, 5.9%)	11.1% (7.8%, 15.8%)	24.5%
Inter-mediate	[21, 36)	27.3	3	559	[21, 35]	5.7% (4.0%, 8.2%)	13.4% (9.6%, 18.5%)	26.3%
High	[36, 58)	44.2	4	316	[36, 57]	7.4% (4.9%, 11.1%)	21.1% (13.7%, 31.7%)	14.8%
High	[58, 100]	78.6	5	218	[58, 100]	13.6% (9.3%, 19.5%)	34.2% (24.4%, 46.4%)	10.2%
Total		26.7		2,129	[0, 100]	5.4% (4.5%, 6.5%)	13.5% (11.4%, 15.9%)	100.0%

Table Footnote: Analysis includes one (n=1) case imaged on a Toshiba MRI scanner.

e. Study Population

Subject demographics for the clinical validation dataset are compared to the U.S. population in the table below. The validation population is broadly representative of intended use population (Stage I-IIIa, HR+/HER2- early stage or locally advanced breast

TumorSight Risk 510(k) Summary

carcinoma). Notably, all input variables were available for all samples in the clinical validation study.

Table 5: Demographics of US Population along with the validation dataset. Patient demographics in the validation dataset demonstrate that the algorithm was developed on a population that is representative of the intended use population. Dataset has representation across age, race/ethnicity, cancer subtype, histology, grade, T stage and N stage.

Factor	US Population (%)	Validation N=2,129 (%)
Institution		
Site 7	-	712 (33.4%)
Site 8	-	718 (33.7%)
Site 9	-	447 (21.0%)
Site 10	-	252 (11.8%)
Age*		
22-29	<1%	16 (<1%)
30-39	4%	128 (6%)
40-49	13%	505 (24%)
50-59	22%	580 (27%)
60-69	29%	567 (27%)
70-79	21%	300 (14%)
80+	11%	33 (2%)
Race**		
White	71%	1,532 (72%)
Black or African American	12%	338 (16%)
Asian	5%	182 (9%)
Native Hawaiian or Other Pacific Islander†	<1%	65 (3%)
American Indian or Alaska Native†	1%	6 (<1%)
Other†	10%	6 (<1%)
Unknown†	-	0 (0%)
Cancer Grade*		
1	21%	736 (35%)
2	42%	1,084 (50%)
3	29%	309 (15%)
Unknown	8%	0 (0%)
Clinical Tumor Stage***		
T1	55%	1,299 (61%)
T2	31%	681 (32%)
T3	8%	149 (7%)
T4	1%	0 (0%)
Unknown	6%	0 (0%)
Clinical Nodal Stage***		
N0	66%	1,811 (85%)
N1	25%	318 (15%)
N2	6%	0 (0%)

TumorSight Risk 510(k) Summary

N3	0%	0 (0%)
Unknown	3%	0 (0%)
Breast Laterality[†]		
Left	50.8%	1065 (50%)
Right	49.2%	1064 (50%)
Recurrence (Any Time)		
True	-	181 (8.5%)
False	-	1,948 (91.5%)

Table Footnote:

* US population age and grade statistics are from: Gianquinto, AN, Hyuna Sung, Kimberly D. Miller, et al. Breast Cancer Statistics, 2022. *CA: A Canc J for Clins.*, 2022; 72(6):524-541. doi:10.3322/caac.21754

** US population race statistics from: U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; <https://www.cdc.gov/cancer/dataviz>, released in June 2025.

*** US population Tumor and Nodal stage statistics from: American Cancer Society. *Breast Cancer Facts & Figures 2024-2025*. Atlanta: American Cancer Society; 2024.

[†] Within the TumorSight Risk device and algorithm, races other than White and Black are categorized as “Other”.

[‡] Laterality statistics are from: Abdou, Y., Gupta, M., Asaoka, M. et al. Left sided breast cancer is associated with aggressive biology and worse outcomes than right sided breast cancer. *Sci Rep* 12, 13377 (2022)

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 Risk software, outweigh the device residual risks.

Substantial Equivalence Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

The subject device (TumorSight Risk) is substantially equivalent to the identified predicate device, ArteraAI Breast (K254115), classified under 21 CFR 864.3755 – Pathology software algorithm device analyzing digital images for breast cancer prognosis.

The subject device has the same intended use and similar indications for use as the predicate. Both devices are prescription-use software devices that analyze acquired digital images from patients with previously diagnosed breast cancer to generate prognostic risk estimates intended to support risk-based patient management decisions. Neither device is intended to establish a clinical diagnosis.

Both devices also use the same fundamental technological approach, namely the application of software algorithms to analyze digital images for breast cancer prognostic purposes. Both device provide the clinical end user with prognostic information within a timeframe that is clinically meaningful to its indicated clinical condition. For both devices, the prognostic information is intended to assist clinicians in patient management decisions, it is intended to supplement, not replace, clinical decision-making, and is used in conjunction with other clinical information.

The technological characteristics and intended use of TumorSight Risk are associated with the same risks as the predicate device, and can be mitigated in a similar fashion to the predicate device:

TumorSight Risk 510(k) Summary

<u>Risks to Health</u>	<u>Mitigation Measures</u>
Risk of false positive, false negative, or failure to provide a result.	Certain design verification and validation activities, including certain analytical and clinical studies. Certain labeling information, including certain performance information and limitations.
Incorrect interpretation of test results by the user.	Certain design verification and validation activities. Certain labeling information, including certain performance information and limitations.

Additionally, TumorSight Risk meets all special controls for 21 CFR 864.3755.

Based on the same intended use, similar indications for use and technological characteristics, and classification under the same regulation, the subject device is substantially equivalent to the predicate device.

Substantial Equivalence Information

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

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

Table 6: Predicate Device Comparison

	ArteraAI Breast (Predicate Device)	TumorSight Risk (Subject Device)
Submission Number	K254115	K260023
Manufacturer	Artera Inc.	SimBioSys, Inc.
Regulation Number	21 CFR 864.3755	Same as predicate
Regulation Name	Pathology software algorithm device analyzing digital images for breast cancer prognosis	Same as predicate
Device Classification	Class II	Same as predicate
Product Code	SHW	Same as predicate
Indications of Use	ArteraAI Breast is a software only device intended to analyze scanned histopathology whole slide image (WSI) from treatment-naïve breast resection specimens prepared from formalin fixed paraffin-embedded (FFPE) tissue and stained using Hematoxylin & Eosin (H&E) stains. Additional inputs to ArteraAI Breast include the following physician-provided clinical variables: • Age • Tumor size • Nodal status ArteraAI Breast provides 5- and 10-year	TumorSight Risk is an artificial intelligence based software only device that analyzes data from previously diagnosed invasive breast cancer patients to assess the risk of recurrence. TumorSight Risk utilizes the following data: age, race, cancer stage, nodal status, and grade, combined with Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI) data to generate 5- and 10-year risks of breast cancer recurrence and a proprietary prognostic score. TumorSight Risk is intended for use in

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	risks of distant metastasis and ArteraAI risk score for adult patients with HR+/HER2-, N0 or N1, early-stage invasive breast cancer without clinically or pathologically defined metastases after surgical tumor resection and who are candidates for standard of care adjuvant therapy. ArteraAI Breast is intended to assist physicians with prognostic risk-based decisions along with other clinicopathological factors. ArteraAI Breast is intended to utilize WSIs acquired from FDA-cleared interoperable scanners and file formats that have been validated for use with this device.	adult women with hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-), lymph node negative (N0) or positive (N1), Stage I-III breast cancer to inform a physician in prognostic risk-based decisions in conjunction with other relevant clinicopathological factors.
Data Source (Input)	Scanned histopathology whole slide images (WSIs) from treatment-naïve breast resection specimens prepared from formalin fixed paraffin embedded (FFPE) tissue and stained using Hematoxylin & Eosin (H&E) stains	DCE-MRI and Clinicopathological data
Output	5-year and 10-year risks of distant metastasis for diagnosed invasive breast cancer patients.	5-year and 10-year risk of recurrence for previously diagnosed invasive breast cancer patients.
Output Accessibility	Graphic and text results of risk of recurrence of breast cancer are accessed via a device with internet connectivity	Same as predicate
Physical Characteristics	Software as a Medical Device with artificial intelligence/machine learning (AI/ML) function	Same as predicate
Safety	Clinician review and assessment of device output prior to use in treatment planning.	Same as predicate