Therapixel
Shalyna Long Bansropun
Head of Quality Assurance and Regulatory Affairs
455 Promenade des Anglais,
06200 Nice
France

June 26, 2026

Re: K260714
Trade/Device Name: MammoScreen® (5)
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ, QIH
Dated: June 17, 2026
Received: June 17, 2026

Dear Shalyna Long Bansropun:

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); 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,

Digitally signed by Michael D. O'hara -S
Date: 2026.06.26 15:08:43 -04'00'

For

Yanna Kang
Assistant Director
Mammography and Ultrasound Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260714

Please provide the device trade name(s).

MammoScreen® (5)

Please provide your Indications for Use below.

MammoScreen 5 is a concurrent reading and reporting aid for physicians interpreting screening mammograms. It is intended for use with compatible full-field digital mammography and digital breast tomosynthesis systems. The device can also use compatible prior examinations in the analysis.
Output of the device includes graphical marks of findings as soft-tissue lesions or calcifications on mammograms along with their level of suspicion scores. The lesion type is characterized as mass/ asymmetry, distortion, or calcifications for each detected finding. The level of suspicion score is expressed at the finding level, for each breast, and overall for the mammogram.
The location of findings, including quadrant, depth, and distance from the nipple, is also provided. This adjunctive information is intended to assist interpreting physicians during reporting.
Patient management decisions should not be made solely based on the analysis by MammoScreen 5.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary | K260714

MammoScreen®

This 510(k) summary of safety and effectiveness information is prepared in accordance with the requirements of 21 CFR § 807.92.

Applicant Information:

Therapixel
455 Promenade des Anglais,
06200 Nice
France
Phone: +33 9 72 55 20 39

Company Representative:

Pierre Fillard
Chief Scientific Officer
Email: pfillard@therapixel.com
Phone: +33 6 83 71 28 09

Primary Correspondent:

Shalyna Bansropun
Head of Quality Assurance & Regulatory Affairs
Email: sbansropun@therapixel.com
Phone: + 33 6 20 15 11 13

Date Summary Prepared: March 02, 2026

Device Information:

Trade Name:	MammoScreen®
Model;	5
Common Name:	Computer-Assisted Detection Device
Device Classification Name:	Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer
Regulation Number:	892.2090
Regulation Class:	Class II
Product Code:	QDQ
Associated Product Code:	QIH
Submission type:	Special 510(k)
510(k) number:	K260714

Predicate Device:
The predicate device is MammoScreen 4, cleared under K243679 (Product code QDQ).

Device Description
MammoScreen® 5 is a concurrent reading medical software device using artificial intelligence to assist radiologists in the interpretation of mammograms.

MammoScreen® 5 processes the mammogram(s) and detects findings suspicious for breast cancer. Each detected finding gets a score called the **MammoScreen Score™**. The score was designed such that findings with a low score have a very low level of suspicion. As the score increases, so does the level of suspicion. For each mammogram, **MammoScreen® 5** outputs detected findings with their associated score, a score per breast, driven by the highest finding score for each breast, and a score per case, driven by the highest finding score overall. The **MammoScreen Score™** goes from one to ten.

MammoScreen® 5 is available for 2D (FFDM images) and 3D processing (FFDM & DBT or DBT) for GE® and Hologic® devices. Optionally, **MammoScreen® 5** can use prior examinations in the analysis.

MammoScreen® 5 can also aid in the reporting process by populating an initial report with chosen findings, including lesion type and position (quadrant, depth and distance to nipple).

Note that the **MammoScreen® 5** outputs should be used as complementary information by radiologists while interpreting mammograms. For all cases, the medical professional interpreting the mammogram remains the sole decision-maker.

Indication for Use
MammoScreen® 5 is a concurrent reading and reporting aid for physicians interpreting screening mammograms. It is intended for use with compatible full-field digital mammography and digital breast tomosynthesis systems. The device can also use compatible prior examinations in the analysis.

Output of the device includes graphical marks of findings as soft-tissue lesions or calcifications on mammograms along with their level of suspicion scores. The lesion type is characterized as mass/asymmetry, distortion, or calcifications for each detected finding. The level of suspicion score is expressed at the finding level, for each breast, and overall for the mammogram.

The location of findings, including quadrant, depth, and distance from the nipple, is also provided. This adjunctive information is intended to assist interpreting physicians during reporting.

Patient management decisions should not be made solely based on analysis by MammoScreen® 5.

Intended user population
Intended users of MammoScreen are physicians qualified to read mammograms.

Intended patient population

The device is intended to be used in the population of women undergoing mammography.

Warnings and precautions

Patient management decisions should not be made solely based on analysis by MammoScreen.

Predicate device comparison

	PREDICATE DEVICE	SUBJECT DEVICE	Comparison
	MammoScreen 4	**MammoScreen 5**	
Manufacturer	Therapixel	Therapixel	Identical
Classification Regulation	21 CFR 892.2090 Radiological Computer Assisted Detection And Diagnosis Software	21 CFR 892.2090 Radiological Computer Assisted Detection And Diagnosis Software	Identical
Medical Device Classification	Class II	Class II	Identical
Product Code	QDQ	QDQ	Identical
Intended Use	MammoScreen® 4 is a concurrent reading and reporting aid for physicians interpreting screening mammograms. It is intended for use with compatible full-field digital mammography and digital breast tomosynthesis systems. The device can also use compatible prior examinations in the analysis. Output of the device includes graphical marks of findings as soft-tissue lesions or calcifications on mammograms along with their level of suspicion scores. The lesion type is characterized as mass/asymmetry, distortion, or calcifications for each detected finding. The level of suspicion score is expressed at the finding level, for each breast, and overall for the mammogram.	MammoScreen® 5 is a concurrent reading and reporting aid for physicians interpreting screening mammograms. It is intended for use with compatible full-field digital mammography and digital breast tomosynthesis systems. The device can also use compatible prior examinations in the analysis. Output of the device includes graphical marks of findings as soft-tissue lesions or calcifications on mammograms along with their level of suspicion scores. The lesion type is characterized as mass/asymmetry, distortion, or calcifications for each detected finding. The level of suspicion score is expressed at the finding level, for each breast, and overall for the mammogram.	Identical

	PREDICATE DEVICE	SUBJECT DEVICE	Comparison
	MammoScreen 4	**MammoScreen 5**	
	The location of findings, including quadrant, depth, and distance from the nipple, is also provided. This adjunctive information is intended to assist interpreting physicians during reporting. Patient management decisions should not be made solely based on the analysis by MammoScreen® 4.	The location of findings, including quadrant, depth, and distance from the nipple, is also provided. This adjunctive information is intended to assist interpreting physicians during reporting. Patient management decisions should not be made solely based on the analysis by MammoScreen® 5.	
Intended user population	Physicians qualified to read mammograms	Physicians qualified to read mammograms	Identical
Intended patient population	Women undergoing mammography.	Women undergoing mammography.	Identical
Anatomical Location	Breast	Breast	Identical
Design	Software-only device	Software-only device	Identical
Type of artificial intelligence	MammoScreen 4 is powered by artificial intelligence/machine learning-based software algorithm	MammoScreen 5 is powered by artificial intelligence/machine learning-based software algorithm	Identical
Level of suspicion	MammoScreen 4 outputs a level of suspicion at the finding, breast and case level.	MammoScreen 5 outputs a level of suspicion at the finding, breast and case level.	Identical
Lesion type	For each detected finding MammoScreen 4 classifies them as mass/asymmetry, distortion or calcifications.	For each detected finding MammoScreen 5 classifies them as mass/asymmetry, distortion or calcifications.	Identical

<table>
<tr><th></th><th>PREDICATE DEVICE</th><th>SUBJECT DEVICE</th><th rowspan="2">Comparison</th></tr>
<tr><th></th><th>MammoScreen 4</th><th>MammoScreen 5</th></tr>
<tr><td>Location of findings</td><td>Marks and description including quadrant, depth, and distance from the nipple.</td><td>Marks and description including quadrant, depth, and distance from the nipple.</td><td>Identical</td></tr>
<tr><td>Localization</td><td>For each finding MammoScreen 4 provides a quadrant, a depth and a distance to the nipple.</td><td>For each finding MammoScreen 5 provides a quadrant, a depth and a distance to the nipple.</td><td>Identical</td></tr>
<tr><td>Inputs</td><td>FFDM or 2DSM & DBT or FFDM & DBT, with an optional prior (FFDM or 2DSM & DBT) expect for the former</td><td>FFDM and/or DBT, with an optional prior (FFDM or DBT).</td><td>Since a tomosynthesis acquisition consistently produces both DBT images and a synthetic 2D mammography image (2DSM), terminology used for these modalities has been simplified</td></tr>
<tr><td>Supported Scenarios</td><td>• Cross-modality/prior comparison scenarios:</td><td>• Cross-modality/prior comparison scenarios:
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="3">Current</th></tr>
<tr><th>FFDM</th><th>DBT</th><th>DBT+FFDM</th></tr>
<tr><td colspan="2">No Prior</td><td>Supported**</td><td>Supported*</td><td>Supported</td></tr>
<tr><td rowspan="3">Prior</td><td>FFDM</td><td rowspan="3">Supported in V5</td><td>Supported in V5</td><td>Supported</td></tr>
<tr><td>DBT+FFDM</td><td rowspan="2">Supported</td><td rowspan="2">Supported in V5</td></tr>
<tr><td>DBT</td></tr>
</table>
*Only combination supported with Hologic Envision™</td><td>New supported scenarios that do not raise different questions</td></tr>
</table>

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<tr><td colspan="2"></td><td>FFDM</td><td>DBT</td><td>2DSM</td><td>DBT+FFDM</td><td>DBT+2DSM</td></tr>
<tr><td>No Prior</td><td>/</td><td>Supported</td><td>Unsupported</td><td>Unsupported</td><td>Supported</td><td>Supported*</td></tr>
<tr><td rowspan="5">Prior</td><td>FFDM</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Supported</td><td>Unsupported</td></tr>
<tr><td>DBT</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td></tr>
<tr><td>2DSM</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td></tr>
<tr><td>DBT + FFDM</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td></tr>
<tr><td>DBT + 2DSM</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Unsupported</td><td>Supported</td></tr>
</table>
*Only combination supported with Hologic Envision™</td><td>**Not Supported for GE

• Supplementary views (XCCM, XCCL, ML)
• Duplicated views</td><td>about the safety and effectiveness of the device as compared to the predicate device.
The devices have the same intended use.</td></tr>
<tr><td>Inclusion of PCCP</td><td>Included. The PCCP in the predicate device includes proposed modifications related to extending supported image acquisition systems</td><td>No new PCCP included</td><td>-</td></tr>
</table>

The indication for the use of MammoScreen 5 is similar to that of the predicate device. Both devices are intended for concurrent use by physicians interpreting breast images to help them with localizing and characterizing findings. The devices are not intended as a replacement for the review of a physician or their clinical judgment.

The predicate device and the subject device are two software versions of MammoScreen. They both rely on the same fundamental scientific technology. The design changes of this new version of MammoScreen have been assessed at the software design level and do not raise different questions of safety and effectiveness than the previous version. For both devices, a choice of medical image processing and machine learning techniques are implemented. The system includes 'deep learning' modules for the detection of suspicious calcifications and soft tissue lesions. These modules are trained with very large databases of biopsy-proven examples of breast cancer and normal tissue.

The overall design of MammoScreen 5 is the same as the design of the predicate device. Both versions detect and characterize findings in radiological breast images and provide information about the presence, location, and characteristics of the findings to the user in a similar manner. While MammoScreen 5, corrects some bugs found in the predicate device, and aims to demonstrate via a standalone performance analysis that MammoScreen can be validated on several scenarios, these modifications do not raise different questions about the safety and effectiveness of the device as compared to the predicate device. The devices have the same intended use. The safety and effectiveness of the device have been evaluated with a similar methodology as for the predicate device.

Non clinical Testing

MammoScreen is a software-only device.

Tests have been performed in compliance with the following recognized consensus standards:

- IEC 62304:2006/A1:2016- Medical device software - Software life-cycle processes
- IEC 62366-1:2015+AMD1:2020- Medical devices - Application of usability engineering to medical devices.

MammoScreen 5 has successfully completed integration and verification testing. In addition, potential hazards have been evaluated and mitigated and have acceptable levels.

The algorithm behind MammoScreen 5 did not change/evolve compared to its predecessor, accordingly a standalone performance testing was deemed sufficient to validate and claim compatibility with the newly introduced scenarios.

The standalone performance testing is summarized in what follows:

Statistics tests for primary objective	Non-inferiority in standalone cancer detection performance on newly introduced scenarios compared to scenarios already supported				
Primary endpoint	**Supplementary views**				
	Metric/Level	**Including EV**	**Excluding EV (ref.)**	**Δ**	**p-value**
	AUCROC Mammogram level	0.911 (0.894, 0.928)	0.894 (0.874, 0.914)	0.017 (0.007, 0.027)	0.000
	AUCROC Breast level	0.926 (0.910, 0.941)	0.912 (0.894, 0.929)	0.014 (0.004, 0.023)	0.000
	AUCLROC Finding level	0.909 (0.888, 0.930)	0.895 (0.872, 0.917)	0.014 (0.005, 0.023)	0.000
	Duplicated views				
	Metric/Level	**Including duplicates**	**Excluding duplicates (ref.)**	**Δ**	**p-value**
	AUCROC Mammogram level	0.920 (0.907, 0.932)	0.907 (0.893, 0.920)	0.013 (0.006, 0.020)	0.000
	AUCROC Breast level	0.938 (0.927, 0.948)	0.927 (0.916, 0.939)	0.010 (0.005, 0.016)	0.000
	AUCLROC Finding level	0.908 (0.892, 0.924)	0.900 (0.884, 0.916)	0.007 (-0.000, 0.015)	0.000
	Current/Prior scenario: DBT+FFDM with prior DBT				
	Metric/Level	**DBT+FFDM with prior DBT**	**DBT+FFDM with prior FFDM (ref.)**	**Δ**	**p-value**
	AUCROC Mammogram level	0.951 (0.937, 0.965)	0.955 (0.943, 0.968)	-0.004 (-0.011, 0.002)	0.000
	AUCROC Breas level	0.955 (0.942, 0.968)	0.957 (0.943, 0.971)	-0.002 (-0.007, 0.003)	0.000
	AUCLROC Finding level	0.936 (0.917, 0.956)	0.935 (0.914, 0.956)	0.001 (-0.007, 0.009)	0.000
	Current/Prior scenario: DBT with prior FFDM				
	Metric/Level	**DBT+FFDM with prior DBT**	**DBT+FFDM with prior FFDM (ref.)**	**Δ**	**p-value**
	AUCROC Mammogram level	0.951 (0.937, 0.965)	0.955 (0.943, 0.968)	-0.004 (-0.011, 0.002)	0.000
	AUCROC Breas level	0.955 (0.942, 0.968)	0.957 (0.943, 0.971)	-0.002 (-0.007, 0.003)	0.000
	AUCLROC Finding level	0.936 (0.917, 0.956)	0.935 (0.914, 0.956)	0.001 (-0.007, 0.009)	0.000
	Current/Prior scenario: FFDM with prior FFDM				
	Metric/Level	**DBT with prior FFDM**	**DBT with prior DBT* (ref.)**	**Δ**	**p-value**
	AUCROC Mammogram level	0.937 (0.922, 0.952)	0.932 (0.916, 0.948)	0.005 (-0.002, 0.012)	0.000
	AUCROC Breas level	0.941 (0.924, 0.957)	0.932 (0.913, 0.950)	0.009 (0.000, 0.018)	0.000
	AUCLROC Finding level	0.913 (0.891, 0.936)	0.902 (0.878, 0.927)	0.011 (0.001, 0.021)	0.007
	Current/Prior scenario: FFDM with prior DBT				
	Metric/Level	**FFDM with prior DBT**	**FFDM no prior**	**Δ**	**p-value**
	AUCROC Mammogram level	0.864 (0.838, 0.890)	0.869 (0.844, 0.894)	-0.005 (-0.013, 0.004)	0.000

	AUCROC Breas level	0.882 (0.858, 0.905)	0.884 (0.860, 0.908)	-0.002 (-0.008, 0.004)	0.000
	AUCLROC Finding level	0.803 (0.767, 0.838)	0.807 (0.771, 0.844)	-0.005 (-0.015, 0.006)	0.000
Acceptance criteria	Positive lower bound of the 95% CI of the difference in endpoints between the scenario under evaluation (introduced with MammoScreen 5) and the reference scenario (already cleared with MammoScreen 4).				
Number of included patients	9,789				
Number of included studies	9,789				
Age distribution	*Age <= 50*: 2,383 *50 < Age <= 65*: 3,091 *65 > Age:* 1,614				
Race and Ethnicity distribution	*Asian:* 652 *White:* 2,295 *Black:* 961 *Other (including American Indian, Alaska Native, Native Hawaiian or Other Pacific Islander):* 467 *Hispanic:* 328 *Not reported:* 9,461				
Considered subgroups	Density, Lesion type (mass/asymmetries, calcifications, distortion), Age, Lesion size, Lesion severity, Race, Ethnicity, Data provenance, Reference standard for negative cases, Current image combination, Prior image type, Acquisition year, Presence of a non-standard view				
Truthing process	Positive cases: biopsy-proven presence of cancer Benign cases: - For non-biopsied cases: verified by imaging follow-up. - For biopsied cases: confirmed by biopsy result AND imaging follow-up. Negative cases: verified by imaging follow-up.				
Independence of tests data from training data	Data sources are separated into the training/tuning group and the test group. Sources in the training/tuning group may only be used for model training and tuning. Sources in the test group may only be used for external validation of the model's performances on unseen data (i.e., from sources entirely left out during training and tuning). Data used for the standalone performance testing only belongs to the test group.				

Please note that no new usability engineering tests have been performed for MammoScreen 5 as those already submitted for the previously cleared device MammoScreen 3 (K240301) are still applicable.

The above testing confirmed that MammoScreen 5 performs in accordance with the stated intended use. All data fell within pre-determined product specifications and external standard requirements. Results of testing confirmed the substantial equivalence of the MammoScreen 5 to the predicate device.

Clinical Testing

Therapixel has provided documentation concerning the clinical testing to support the premarket submission for the previously cleared device MammoScreen 3 (K240301).

The clinical study results from K240301 remain fully applicable to the subject device (MammoScreen 5). No additional clinical studies were conducted to support substantial equivalence to the predicate device (MammoScreen 4). Aside from the data included in the previous submissions, no new or additional clinical testing documentation is included in this submission, as the existing data continues to demonstrate the safety and effectiveness of the device.

Conclusions

Standalone performance tests on FFDM and DBT (with and without prior) demonstrate that MammoScreen 5 achieves non-inferior performance compared to the predicate device.

Previous MRMC studies and standalone tests have demonstrated that the device is safe and effective.

Therapixel has applied a risk management process following FDA-recognized standards to identify, evaluate, and mitigate all known hazards related to MammoScreen 5. These hazards may occur when the accuracy of diagnosis is potentially affected, causing either false positives or false negatives. All identified risks are effectively mitigated, and it can be concluded that the residual risk is outweighed by the benefits. Considering all data in this submission, the data provided in these 510(k) supports the safe and effective use of MammoScreen 5 for its indications for use and substantial equivalence to the predicate device.