November 26, 2021

Therapixel
℅ Ms. Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroichet Drive
HILLSBOROUGH CA 94010

Re: K211541
Trade/Device Name: MammoScreen® 2.0
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QDQ
Dated: November 19, 2021
Received: November 22, 2021

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211541

Device Name
MammoScreen® 2.0

Indications for Use *(Describe)*
MammoScreen® is intended for use as a concurrent reading aid for interpreting physicians, to help identify findings on screening FFDM and DBT acquired with compatible mammography systems and assess their level of suspicion. Output of the device includes marks placed on findings on the mammogram and level of suspicion scores. The findings could be soft tissue lesions or calcifications. The level of suspicion score is expressed at the finding level, for each breast and overall for the mammogram. Patient management decisions should not be made solely on the basis of analysis by MammoScreen®.

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

K211541

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

Applicant Information:

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Date Summary Prepared: November 25th, 2021

Device Information:

Trade Name:	MammoScreen 2.0
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
Submission type	Traditional 510(k)
510(k) number:	K211541

Predicate Device:

The predicate device is MammoScreen, cleared under K192854.

Device Description:

MammoScreen 2.0 automatically processes the four views (one CC and one MLO per breast) of standard screening FFDM or DBT, and outputs a corresponding report on a separate screen, alongside the monitors used for reading. This report is designed to be easily readable with very few interactions required by providing an overall level of suspicion of each exam and giving explicit visual indications when highly suspicious exams are detected.

MammoScreen 2.0 detects and characterizes findings on a scale from one to ten, referred to as 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.

Furthermore, MammoScreen 2.0 provides a high level of interpretability. Results are by construction consistent at the finding, breast and mammogram level. A breast takes on the highest score of its detected findings, and the level of suspicion for the exam is driven by the breast(s) with the highest score. Therefore, it is always possible to track a high suspicion of malignancy for an exam to the corresponding breast(s), and to a specific finding within the breast(s).

Indication for Use:

MammoScreen is intended for use as a concurrent reading aid for interpreting physicians, to help identify findings on screening FFDM or DBT acquired with compatible mammography systems, and assess their level of suspicion. Output of the device includes marks placed on findings on the mammogram and level of suspicion scores. The findings could be soft tissue lesions or calcifications. The level of suspicion score is expressed at the finding level, for each breast and overall for the mammogram. Patient management decisions should not be made solely on the basis of analysis by MammoScreen.

Intended user population

Intended users of MammoScreen are physicians qualified to read screening mammograms.

Intended patient population

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

Warnings and precautions

Patient management decisions should not be made solely on the basis of analysis by MammoScreen.

Predicate device comparison:

The indication for use of MammoScreen 2.0 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 judgement. Use of the device with DBT has been added in the indications for use of the subject device compared to the indications for use of the predicate device. The algorithmic components have been updated to improve detection accuracy for FFDM and to enable processing of DBT. The overall design of MammoScreen 2.0 is the same as that 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. The modifications do not raise different questions of safety and effectiveness of the device as compared to the predicate device.

Non clinical Testing

MammoScreen is a software-only device. The level of concern for the device is determined as Moderate Level of Concern.

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 2.0 has successfully completed integration and verification testing and beta validation. In addition, potential hazards have been evaluated and mitigated, and have acceptable levels.

Clinical Testing

Clinical validation of MammoScreen 2.0 included two reader studies (one for each modality: FFDM and DBT) with similar designs and methodologies.

Hereafter, unless differences are explicitly detailed, the description will refer to both studies.

The reader studies used a multi-reader multi-case (MRMC) cross-over design with an enriched sample set of 240 cases with MQSA-qualified and ABR-certified readers (14 for the 2D study and 20 for the 3D study) to compare the performance of unaided radiologists to that of radiologists using MammoScreen.

The objectives of the studies were to determine:

- Whether the radiologist performance when using MammoScreen is superior to unaided radiologist performance for interpretation of screening mammograms (*primary objective*).
- Whether the performance of MammoScreen standalone is superior to unaided radiologist performance.
- Whether the performance of MammoScreen standalone is non-inferior to aided radiologist performance.

All performances were intended at mammogram, breast and finding level and assessed by measuring the Area Under the Receiver Operating Characteristic (ROC) Curve (AUC).

Radiologists improved their diagnostic performance in the detection of breast cancer with 2D FFDM (Full-Field Digital Mammography) by using MammoScreen. The performance of radiologists taking part in the clinical study was improved when using MammoScreen 2.0, with the average AUC going from 0.77 to 0.80.

The performance of the standalone MammoScreen on FFDM (AUC = 0.79) was found to be non-inferior to the average performance of unaided radiologists (AUC = 0.77).

This MRMC study was conducted on MammoScreen 1.0, the predicate device. Standalone performance tests on subject device demonstrate that MammoScreen 2.0 achieves non-inferior performance compared to the predicate device.

Radiologists improved their diagnostic performance in the detection of breast cancer with DBT (Digital Breast Tomosynthesis) by using MammoScreen. The performance of radiologists taking part in the clinical study was improved when using MammoScreen 2.0, with the average AUC going from 0.79 to 0.83.

The performance of the standalone MammoScreen on DBT (AUC = 0.84) was found to be superior to the average performance of unaided radiologists (AUC = 0.79).

Technological characteristics

	Subject Device	**Predicate Device**	**Substantially Equivalent?**

	MammoScreen (K192854)	MammoScreen 2.0 (K211541)	
Fundamental scientific technology	In MammoScreen, a range of medical image processing and machine learning techniques are implemented. The system includes 'deep learning' modules for recognition 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.	SAME	Yes, identical

The predicate device and the subject device are two versions of the MammoScreen software. They both rely on the same fundamental scientific technology. MammoScreen has been adapted to enable analysis of DBT images. This design change is gauged at the software detailed design level and does not raise different questions of safety and effectiveness by itself.

Conclusions

Standalone performance tests with FFDM demonstrate that MammoScreen 2.0 achieves non-inferior performance compared to the predicate device. For application with DBT, a clinical reader study and standalone tests demonstrated that the device is safe and effective.

Therapixel has applied a risk management process in accordance with FDA recognized standards to identify, evaluate, and mitigate all known hazards related to MammoScreen 2.0. These hazards may occur when 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 this 510(k) support the safe and effective use of MammoScreen 2.0 for its indications for use and substantial equivalence to the predicate device.