May 23, 2023

Hologic, Inc.
% Deborah Thomas
Senior Principal Regulatory Affairs
250 Campus Drive
MARLBOROUGH MA 01730

Re: K230096
Trade/Device Name: Genius AI Detection 2.0 with CC-MLO Correlation
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QDQ
Dated: April 13, 2023
Received: April 13, 2023

Dear Deborah Thomas:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230096

Device Name
Genius AI Detection 2.0 with CC-MLO Correlation

Indications for Use *(Describe)*
Genius AI Detection is a computer-aided detection and diagnosis (CADe/CADx) software device intended to be used with compatible digital breast tomosynthesis (DBT) systems to identify and mark regions of interest including soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in DBT exams from compatible DBT systems and provide confidence scores that offer assessment for Certainty of Findings and a Case Score. The device intends to aid in the interpretation of digital breast tomosynthesis exams in a concurrent fashion, where the interpreting physician confirms or dismisses the findings during the reading of the exam.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k)
Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: January 12, 2023

Manufacturer:
Hologic, Inc.
36 Apple Ridge
Road Danbury, CT
06810 USA

Establishment Registration #: 1220984

Contact Person:
Deborah Thomas
Senior Principal Regulatory Affairs
P: 508.210.6107

Identification of the Device:

Proprietary/Trade Name:	Genius AI Detection 2.0 with CC-MLO Correlation
Classification Name:	Radiological Computer Assisted Detection/Diagnosis Software for Lesions Suspicious for Cancer
Regulatory Number:	21 CFR 892.2090
Product Code:	QDQ
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate and Reference Devices:

Predicate Device	Genius AI Detection 2.0
Trade Name:	Radiological Computer Assisted Detection/Diagnosis
Classification Name:	Software for Lesions Suspicious for Cancer
	21 CFR 892.2090
Regulatory Number:	QDQ
Product Code:	Class II
Device Class:	Radiology
Review Panel:	Hologic, Inc.
Submitter/510(k)	K221449 (cleared October 6, 2022)
Holder: Clearance:	
Reference Device	Transpara 1.7.2
Trade Name:	Radiological Computer Assisted Detection/Diagnosis
Classification Name:	Software for Lesions Suspicious For Cancer

Regulatory Number:	21 CFR 892.2090
Product Code:	QDQ
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	ScreenPoint Medical B.V
Clearance:	K221347 (cleared August 3, 2022)

Device Description:
Genius AI Detection is a software device intended to identify potential abnormalities in breast tomosynthesis images. Genius AI Detection analyzes each standard mammographic view in a digital breast tomosynthesis examination using deep learning networks. For each detected lesion, Genius AI Detection produces CAD results that include the location of the lesion, an outline of the lesion and a confidence score for that lesion. Genius AI Detection also produces a case score for the entire tomosynthesis exam.

Genius AI Detection packages all CAD findings derived from the corresponding analysis of a tomosynthesis exam into a DICOM Mammography CAD SR object and distributes it for display on DICOM compliant review workstations. The interpreting physician will have access to the CAD findings concurrently to the reading of the tomosynthesis exam. In addition, a combination of peripheral information such as number of marks and case scores may be used on the review workstation to enhance the interpreting physician's workflow by offering a better organization of the patient worklist.

The Genius AI Detection 2.0 now added the CC-MLO Correlation feature. The added feature provides the ability to correlate a suspected lesion in one view with a like finding in the other view and additionally provides a workflow and navigation feature for the interpreting physician.

Indications for Use:
Genius AI Detection is a computer-aided detection and diagnosis (CADe/CADx) software device intended to be used with compatible digital breast tomosynthesis (DBT) systems to identify and mark regions of interest including soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in DBT exams from compatible DBT systems and provide confidence scores that offer assessment for Certainty of Findings and a Case Score. The device intends to aid in the interpretation of digital breast tomosynthesis exams in a concurrent fashion, where the interpreting physician confirms or dismisses the findings during the reading of the exam.

Standards:
- IEC 62304: 2015 – Medical device software – Software Life Cycle Processes (#13-79)
- ISO 14971: 2012 – Medical devices – Application of Risk Management to Medical Devices
- DEN180005 Evaluation of automatic class III designation for OsteoDetect – Decision summary with special controls.

FDA Guidance Documents:

- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued on May 11, 2005)
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data –
  Premarket Notification [510(k)] Submissions (Issued on July 3, 2012)
- Guidance for Industry and FDA Staff - Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions (Issued on January 22, 2020)
- "Off-the-Shelf Software Use in Medical Devices," issued on September 9, 1999
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued on October 2, 2014.

Summary of Substantial Equivalence:

Features and Characteristics	**Subject Device Hologic, Inc. Genius AI Detection 2.0 with CC-MLO Correlation**	**Predicate Hologic, Inc. Genius AI Detection 2.0**	**Reference Device ScreenPoint Medical Transpara 1.7.2**	**Difference and comments**
510(k) Number	pending	K221449	K221347	N/A
Regulation Number/Name	21 CFR 892.2090 / Radiological Computer Assisted Detection and Diagnosis Software	Same	Same	N/A
Product Code	QDQ	Same	Same	N/A

Indications for Use	Genius AI Detection is a computer-aided detection and diagnosis (CADe/CADx) software device intended to be used with compatible digital breast tomosynthesis (DBT) systems to identify and mark regions of interest including soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in DBT exams from compatible DBT systems and provide confidence scores that offer assessment for Certainty of Findings and a Case Score. The device intends to aid in the interpretation of digital breast tomosynthesis exams in a concurrent fashion, where the interpreting physician confirms or dismisses the findings during the reading of the exam.	Same	Transpara software is intended for use as a concurrent reading aid for physicians interpreting screening full-field digital mammography exams and digital breast tomosynthesis exams from compatible FFDM and DBT systems, to identify regions suspicious for breast cancer and assess their likelihood of malignancy. Output of the device includes locations of calcifications groups and soft-tissue regions, with scores indicating the likelihood that cancer is present, and an exam score indicating the likelihood that cancer is present in the exam. Patient management decisions should not be made solely on the basis of analysis by Transpara.	Similar

Compatible DBT Systems	Hologic Selenia Dimensions Hologic 3Dimensions Supports both models in the following modes: • standard resolution 1-mm slices • high resolution 1-mm slices (Clarity HD) high resolution 6-mm SmartSlices (3DQuorum)	Same	Giotto FFDM General Electric DBT Fujifilm DBT	The predicate and subject device include the support of the following modes on the Hologic DBT systems only: • standard res. 1-mm slices • high res. 1-mm slices . • high resolution 6-mm SmartSlices
Type of CAD Software	Radiological computer assisted detection and diagnostic software.	Same	Same	N/A
Mode of Action	Image processing device utilizing machine learning to aid in the detection, localization, and characterization of soft tissue densities (masses, architectural distortions, and asymmetries) and calcifications in the 1-mm 3D DBT slices. Findings are co-registered to 6-mm SmartSlices.	Same	Software that applies algorithms for recognition of suspicious calcifications and soft tissue lesions to detect and characterize findings in radiological breast images and provide information about the presence, location, and characteristics of the findings to the user.	Similar
Clinical Output	To inform the primary diagnostic and patient management decisions that are made by the clinical user.	Same	Same	N/A

Patient Population	Symptomatic and asymptomatic women undergoing mammography	Same	The device is intended to be used in the population of women undergoing screening mammography and digital breast tomosynthesis.	Similar
End Users	MQSA-Qualified Interpreting Physicians and Radiologists	Same	Intended users of Transpara® are physicians qualified to read screening mammography exams and digital breast tomosynthesis exams.	Similar
Image Source Modalities	Digital breast tomosynthesis slices	Same	Same	N/A
Output Device	Softcopy Workstation	Same	Same	N/A
Deployment	Stand-alone computer	Same	Same	N/A
Method Of Use	Concurrent read	Same	Same	N/A
Visualization Features	Places mark within suspicious lesion by default (Emphasize™; RightOn™) and reports confidence of finding next to each identified lesion in the image. CAD display may be toggled on/off. Option to automatically zoom into or contour the suspicious region of interest (PeerView™).	Same	Computer aided detection (CAD) marks to highlight locations where the device detected suspicious calcifications or soft tissue lesions Decision support is provided by region scores on a scale ranging from 0-100, with higher scores indicating a higher level of suspicion.	Similar

Workflow Features	Correlates a suspected lesion in one view with a like finding in the other view, providing a workflow and navigation feature for the interpreting physician.	No correlation of lesions between image views.	Links between corresponding regions in different views of the breast, which may be utilized to enhance user interfaces and workflow.	Similar to the reference device, Genius AI Detection 2.0 with CCMLO provides correlation of the CC and MLO views when a finding is identified.

Comparison with Predicate Device:

The Summary of Substantial Equivalence Table above details the similarities and differences between the Genius AI Detection 2.0 with CC-MLO Correlation device with the predicate Genius AI Detection 2.0, K221449 and reference device Transpara 1.7.2, K221347. Genius AI Detection 2.0 with CC-MLO Correlation is the follow-up release to the predicate, Genius AI Detection 2.0, with the ability to correlate a suspected lesion in one view with a like finding in the other view, providing a workflow and navigation feature for the interpreting physician. Both the proposed and predicate devices use the same technology per 21 CFR 892.2090. Both the predicate device and reference device aid in the detection, localization, and characterization of disease specific findings on acquired medical images. The outputs of the devices serve to augment the interpretation of digital breast tomosynthesis exams as a concurrent reading tool. The output is used to inform and assist the interpreting physician, supplementing their clinical expertise and judgment.

Genius AI Detection 2.0 with CC-MLO Correlation is compatible with the same imaging systems as the predicate device and includes a CC-MLO correlation feature similar to the reference device.

Standalone Performance Testing:

Genius AI Detection 2.0 with CC-MLO Correlation is a software-only device. The level of concern for the device is determined as Moderate Level of Concern.

Verification testing consisted of software validation testing, software integration testing and software system testing. The verification testing showed that the software application satisfied the software requirements.

Standalone evaluation testing was also conducted. The dataset used for this standalone evaluation of the CC-MLO Correlation feature is the same dataset used for the standalone evaluation of the detection performance of Genius AI Detection 2.0 (clearance K221449). This evaluation included 106 biopsy proven malignant cases and 561 screening negative cases.

The 106 biopsied malignant cases included lesions that were marked by an expert radiologist by generating ground truth marks and truth pairs on both orthogonal views (CC and MLO). Each case in this set contained 4 standard mammographic views.

There were 239 individual truth marks in the 106 malignant cases that were analyzed for this evaluation. 226 of those truth marks came from 113 truth pairs which included the lesions that were linked by the radiologist after identifying them on both views.

In addition, the detection pairs generated by the CC-MLO correlation feature on 658 screening negative and biopsied benign cases were reviewed by an expert radiologist.

The performance of the CC-MLO Correlation feature is evaluated by looking at different subgroups including biopsied malignant cases and negative cases. The accuracy of the CC-MLO Correlation feature was estimated in both groups by scoring the detection pairs against the truth pairs and by evaluating the expert radiologist's response, respectively.

Based on results of the verification and evaluation tests, it is concluded that the Genius AI Detection 2.0 with CC-MLO correlation device is safe and effective in detecting soft tissue lesions and calcification lesions and correlating the CC-MLO findings in tomosynthesis exams acquired with Hologic's 3D Mammography systems.

Assessment of Benefit-Risk, Safety and Effectiveness, and Substantial Equivalence:

Risk management is ensured through risk analysis which is used to identify and mitigate potential hazards. Any potential hazards are controlled via software development, verification, and validation testing. In addition, device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Hologic finds that the proposed device has a positive balance in terms of probable benefits vs probable risks and thus may be considered safe and effective based on verification and validation testing.

Conclusion:

Based on the required information submitted in this premarket notification, the proposed Genius AI Detection 2.0 with CC-MLO Correlation device has been found to be substantially equivalent to the predicate Genius AI Detection 2.0, K221449. The devices have similar indications for use and aid in the detection, localization, and characterization of disease specific findings on acquired medical images. There are no issues of safety and effectiveness of the proposed Genius AI Detection 2.0 with CC-MLO Correlation device.