Hologic, Inc.
% Ms. Deborah Thomas
Regulatory Affairs Manager
250 Campus Drive
MARLBOROUGH MA 01752

November 18, 2020

Re: K201019
Trade/Device Name: Genius AI Detection
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QDQ
Dated: October 16, 2020
Received: October 19, 2020

Dear Ms. 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,

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)*
K201019

Device Name
Genius AI Detection

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.

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Traditional 510(k) Summary K201019

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

Date Prepared: November 13, 2020

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

Establishment Registration #: 1220984

Contact Person: Deborah Thomas
Regulatory Affairs Manager
P: 508.210.6107

Identification of the Device:

Proprietary/Trade Name:	Genius AI Detection
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 Device:

Trade Name:	PowerLook Tomo Detection V2 Software
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
Submitter/510(k) Holder:	iCAD
Clearance:	K182373 (cleared December 6, 2018)

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.

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)
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," issued on October 2, 2014
- "Off-the-Shelf Software Use in Medical Devices," issued on September 9, 1999

Summary of Substantial Equivalence:

Features and Characteristics	**Subject Device** Hologic, Inc. Genius AI Detection	**Predicate Device** iCAD Inc. PowerLook® Tomo	**Difference and comments**
Regulation Number/Name	21 CFR 892.2090 / Radiological Computer Assisted Detection and Diagnosis Software	Same	N/A
Product Code	QDQ	Same	N/A
Regulation Description	A radiological computer assisted detection and diagnostic software is an image processing device intended to aid in the detection, localization, and characterization of fracture, lesions, or other disease specific findings on acquired medical images (e.g. radiography, MR, CT). The device detects, identifies and characterizes findings based on features or information extracted from images, and provides information about the presence, location, and characteristics of the findings to the user. The analysis is intended to inform the primary diagnostic and patient management decisions that are made by the clinical user. The device is not intended as a replacement for a complete clinician's review or their clinical judgment that takes into account other relevant information from the image or patient history.	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.	PowerLook® Tomo Detection V2 software is a computer-assisted detection and diagnosis (CAD) software device intended to be used concurrently by interpreting physicians while reading digital breast tomosynthesis (DBT) exams from compatible DBT systems. The system detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices. The detections and Certainty of Finding and Case Scores assist interpreting physicians in identifying soft tissue densities and	
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)	Hologic Selenia Dimensions (standard resolution, 1-mm slices) GE Pristina	The subject device and predicate device are compatible with different systems as noted.
Type of CAD Software	Radiological computer assisted detection and diagnostic software.	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.	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	Co-registration of findings to 6-mm SmartSlices.
Clinical Output	To inform the primary diagnostic and patient management decisions that are made by the clinical user.	same	N/A
Patient Population	Symptomatic and asymptomatic women undergoing mammography	same	N/A
End Users	MQSA-Qualified Interpreting Physicians and Radiologists	same	N/A
Image Source Modalities	Digital breast tomosynthesis slices	same	N/A
Output Device	Softcopy Workstation	same	N/A
Deployment	Stand-alone computer	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™).	Contours suspicious lesions by default and displays confidence of finding next to each identified lesion in the image. CAD display may be toggled on/off. No other marks.	extra display functions of marks

Method Of Use	Concurrent read	Concurrent read. FFDM and 2D synthetic views when available are to be reviewed before	N/A
Supported Views	CC and MLO	same	N/A

Comparison with Predicate Device:
The Summary of Substantial Equivalence Table above details the similarities and differences between the Genius AI Detection device and its predicate device, PowerLook® Tomo Detection V2. Both devices aid in the detection, localization, and characterization of disease specific findings on acquired medical images.

Genius AI Detection is the same technology as the predicate per 21 CFR 892.2090; both devices are radiological computer assisted detection and diagnostic software, intended to aid in the detection, localization, and characterization of disease specific findings on acquired medical images. The outputs of both 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. In the case of any differences that may occur between the subject device and the predicate, rationale for safety and effectiveness is provided above along with special controls established for Radiological Computer Assisted Detection and Diagnosis Software that are in place to further mitigate any risks in these differences.

Compatible DBT Systems

The following image types have been tested and are compatible with Genius AI Detection:

- Hologic standard resolution tomosynthesis slices (1 mm)
- Hologic high resolution tomosynthesis slices (1 mm) (Clarity HD)
- Hologic high resolution SmartSlices (6 mm) (3DQuorum)

The CAD marks generated by Genius AI Detection for the above image types can also be projected on their corresponding synthesized 2D images, providing that the diagnostic review workstation supports such a feature.

Performance Testing – Reader Study Results

The study was successfully executed with all 17 readers; the results below represent a per-protocol analysis of the 390 cases (106 cancers, and 284 negative cases) included in the MRMC where both rounds of reading were completed.

Based on analyses that do not control type I error and therefore cannot be generalized to specific comparisons outside this particular study, in this study:

- The average observed AUC was 0.825 (95% CI: 0.783, 0.867) with CAD and 0.794 (95% CI: 0.748, 0.840) without CAD. The difference in observed AUC was +0.031 (95% CI: 0.012, 0.051).

- The average observed reader sensitivity for cancer cases was 75.9% with CAD and 66.8% without CAD. The difference in observed sensitivity was +9.0% (99% CI: 6.0%, 12.1%).
- The average observed recall rate for non-cancer cases was 25.8% with CAD and 23.4% without CAD. The observed difference in negative recall rate was +2.4% (99% CI: 0.7%, 4.2%).
- The average observed case read-time was 52.0s with CAD and 46.3s without CAD. The observed difference in read-time was 5.7s (95% CI: 4.9s to 6.4s).

Standalone Testing:
Hologic conducted an MRMC reader study to assess the safety and efficacy of Genius AI Detection on Hologic's high resolution tomosynthesis images, where 3D data sets are reconstructed at 70µm. Parallel to the MRMC study, a standalone study was conducted to establish equivalence of Genius AI Detection performance on Hologic's standard resolution tomosynthesis images, where 3D data sets are reconstructed at ~100µm compared to the performance on the high resolution tomosynthesis images. The standalone study was conducted on paired high resolution and standard resolution 3D data sets, where each high-resolution reconstructed 3D volume had a counterpart standard resolution 3D volume, both acquired from a single exposure and under the same compression.

All the results of the standalone study confirmed that Genius AI Detection when operating under the Hologic's standard tomosynthesis acquisition mode performs comparably to when operating under the high-resolution mode.

1. Using an overall data set of 764 cases including 106 cancers and 658 non-cancer cases, Genius AI Detection demonstrated comparable detection performance on both Hologic's standard and high-resolution acquisition modes as observed by fROC analysis.
2. No significant differences were observed in the number and type of cancers detected by Genius AI Detection in either acquisition mode.
3. Stratified fROC analysis using lesion type as well as breast density also showed comparable performance of Genius AI Detection operating in either acquisition mode

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

As a part of the submission, we have demonstrated the probable benefits of the device through clinical study including reader accuracy as assessed by AUC (i.e. diagnostic performance and improved assisted-read detection from the sensitivity analysis. In totality, 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 the special controls established in DEN180005 such that "the device will provide improved assisted-read detection and diagnostic performance."

Conclusion:
Based on the information submitted in this premarket notification, the Genius AI Detection device and its predicate device, PowerLook® Tomo Detection V2 both have a similar intended use and are devices which aid in the detection, localization, and characterization of disease specific findings on acquired medical images. The differences discussed are not significant to the technology and clinical application of the device. The proposed Genius AI Detection device has been found to be substantially equivalent to the predicate PowerLook® Tomo Detection V2 device (K182373).