Hologic, Inc.
Neil Kelly
Principal Regulatory Affairs Specialist
36 Apple Ridge Road
DANBURY, CT 06810

October 20, 2017

Re: K163623
Trade/Device Name: Quantra™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 20, 2016
Received: December 22, 2016

Dear Neil Kelly:

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. 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.

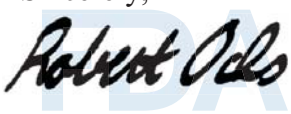
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K163623

Device Name
Quantra™

Indications for Use *(Describe)*
The Quantra™ software application is intended for use with mammographic images acquired using digital breast x-ray systems. The Quantra software segregates breast density into categories, which may be useful in the reporting of consistent BI-RADS® breast composition categories as mandated by certain state regulations. The Quantra software reports a result for each subject, which is intended to aid radiologists in the assessment of breast tissue composition. The Quantra software produces adjunctive information; it is not a diagnostic aid.

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

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

Date Prepared: October 05, 2017

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

Est. Registration #: 1220984

Contact Person: Neil Kelly
Manager, Regulatory Affairs
Phone: (508) 263-8634

Identification of the Device:

Proprietary/Trade Name:	Quantra™
Software Version:	2.2
Classification Name:	System, Image Processing, Radiology
Regulatory Number:	21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade name:	Quantra™
Software Version:	2.1
Classification Name:	System, Image Processing, Radiology
Regulatory Number:	21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K142037 (cleared October 10, 2014)

Device Description:

Quantra is a software application used to produce assessments of breast composition and categorize them. A breast consists of fat and fibroglandular tissue. Fibroglandular tissue, also referred to as dense tissue, contains a mixture of fibrous connective tissue (stroma) and glandular tissue (epithelial cells), and usually appears brighter than surrounding tissue on a digital

mammographic image. Abnormal lesions also appear bright on a mammogram and can be obscured or masked by fibroglandular tissue.

The Quantra software is designed to estimate breast composition categories by analyzing distribution and texture of parenchymal tissue patterns which can be responsible for the masking effect during mammographic reading.

Indications for Use:

The Quantra™ software application is intended for use with mammographic images acquired using digital breast x-ray systems. The Quantra software segregates breast density into categories, which may be useful in the reporting of consistent BI-RADS® breast composition categories as mandated by certain state regulations. The Quantra software reports a result for each subject, which is intended to aid radiologists in the assessment of breast tissue composition. The Quantra software produces adjunctive information; it is not a diagnostic aid.

Standards:
IEC 62304:2006 – Medical Device Software – Software Life Cycle Process
ISO 14971:2012 – Medical Devices – Application of Risk Management to Medical Devices

Comparison with Predicate Device:

The focus of this submission is to introduce improvements in the proposed Quantra software algorithm to align with ACR BI-RADS® Atlas (Fifth Edition, 2013), and to enhance the accuracy of breast composition estimation. To the end user the proposed Quantra software is still used in the exact same way as the predicate Quantra software (K142037). The differences are inherent to the algorithm and reported calculations.

Substantial Equivalence:

	Quantra SW Version 2.1 Predicate (K142037)	**Quantra SW Version 2.2 (Proposed)**	**Comparison**
Indications for Use	Quantra™ is a software application intended for use with images acquired using digital breast x-ray systems. Quantra calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Quantra also provides area breast density as a ratio of	The Quantra™ software application is intended for use with mammographic images acquired using digital breast x-ray systems. The Quantra software segregates breast density into categories, which may be useful in the reporting of consistent BI-RADS® breast composition categories as	Similar

	fibroglandular tissue area and total breast area estimates. Quantra segregates breast density into categories, which may be useful in the reporting of consistent BI-RADS® breast composition categories as mandated by certain state regulations. The Quantra results for each image, breast, and subject, are intended to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information; it is not an interpretive or diagnostic aid.	mandated by certain state regulations. The Quantra software reports a result for each subject, which is intended to aid radiologists in the assessment of breast tissue composition. The Quantra software produces adjunctive information; it is not a diagnostic aid.	
Level of Concern	Moderate	Moderate	Same
Input Modality	Digital x-ray breast images	Digital x-ray breast images	Same
Software Product	Yes	Yes	Same
Reportable Information	• Fibroglandular (dense) Tissue Volume • Total Breast Volume • Volumetric Breast Density • Area Breast Density • Volume of Fibroglandular Tissue Score • Volumetric Breast Density Score • Estimate of Breast Density (integer) • Estimate of Breast Density (fractional)	• Quantra Generated Breast Density Category	Similar. Uses distribution of glandular tissue rather than density of glandular tissue when assessing breast composition.
Statistical comparison to a reference population	Yes	Yes	Same, with the proposed device also being compared against a

			dataset scored to BI-RADS 5th edition.
BI-RADS® Atlas	Yes, 4th Edition 2003	Yes, 5th Edition 2013	Similar, with enhancements
Brest Composition Estimates	Yes, displayed as 1, 2, 3 and 4	Yes, displayed as a, b, c, d	Similar, with enhanced accuracy

Summary of Testing:

Non-clinical (Bench) testing has been performed using retrospectively collected images of 4-view screening negative cases. The proposed Quantra software (Version 2.2) was tested against an independent data set of 230 studies, for which the 5 radiologists' consensus assessment of BIRADS 5th Edition categories are known.

Quantra 2.2 2D Fatty vs. Dense

	Quantra 2.2- QDC 2D				
BI-RADS- 5th Ed.		**Fatty (a+b)**	**Dense (c+d)**	**Per category total**	**Accuracy**
	Fatty (a+b)	105	8	113	92.9%
	Dense (c+d)	1	116	117	99.1%
			Total	230	

Quantra 2.2 Tomo Fatty vs. Dense

	Quantra2.2 – QDC Tomo (3D Center Projection)				
BI-RADS- 5th Ed.		**Fatty (a+b)**	**Dense (c+d)**	**Per category total**	**Accuracy**
	Fatty (a+b)	104	9	113	92.0%
	Dense (c+d)	7	110	117	94.0%
			Total	230	

No animal studies or clinical studies were performed.

Conclusion:
Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the proposed Quantra software (version 2.2) is substantially equivalent to the predicate Quantra software (version 2.1).