DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 10, 2014

Hologic, Inc.
% Ms. Catherine Williams
Sr. Director, Regulatory
2585 Augustine Drive
SANTA CLARA CA 95054

Re: K142037
Trade/Device Name: Quantra
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 25, 2014
Received: July 28, 2014

Dear Ms. Williams:

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 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 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 yours,

for

Janine M. Morris
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142037

Device Name

Quantra™

Indications for Use *(Describe)*

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 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.

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.

510(k) Summary of Safety & Effectiveness

Date Prepared: July 25, 2014

Submitted by:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730 USA

Name, Title and Phone Number of Contact:

Catherine A. Williams
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Trade Name and Common Name:

Trade Name Quantra™
Software Version 2.1
Common Name Picture Archiving and Communications System

Device Classification:

Regulatory Class II
Classification Panel Radiology
Image Processing System 21 CFR §892.2050
Product Code 90-LLZ

Predicate Device:

Quantra 2.0 K120472 (Hologic, Inc.) cleared June 22, 2012.

Predicate Device Description:

The Quantra 2.0 software provides volumetric and area assessment on digital x-ray images of the breast. The Quantra software calculates estimates of breast tissue volumes, estimates of breast tissue areas and statistical measures. The Quantra software operates on a Windows server (e.g., Hologic Cenova server) that meets Quantra data input and output requirements and generally is located outside the patient environment.

Comparison with Predicate Device:

The Quantra 2.1 software provides the same breast density and statistical assessments as Quantra 2.0. The Quantra 2.1 algorithm is updated to make it independent of certain acquisition parameters related to x-ray spectrum and tube output. Quantra 2.1 includes a new reference population with the more recent Hologic Selenia Dimensions image sets. The method to combine image level results for the per-breast and per-patient breast density measures are updated. Specifically, the results are combined by method of averaging versus maximum (in Quantra 2.0).

Intended 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 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.

Technological Characteristics/Device Description:

The Quantra 2.1 software provides volumetric and area assessment on digital x-ray images of the breast. The Quantra software calculates estimates of breast tissue volumes, estimates of breast tissue areas and statistical measures. The Quantra software operates on a Windows server (e.g., Hologic Cenova server) that meets Quantra data input and output requirements and generally is located outside the patient environment. The device does not contact the patient, nor does it control any life-sustaining devices.

Performance/Bench Testing:

Density parameters were evaluated using various image data sets and results were compared against predicate performance, when appropriate.

1) The measurement accuracy for thickness of fibroglandular tissue was assessed using a breast phantom of known composition.
2) The reproducibility of the breast density measurement (Vbd) was assessed using an image dataset of the same patients imaged within a short period of time on two different acquisition systems.
3) All density measures were evaluated statistically between CC and MLO views of the same breast and left and right breasts of the same women, using a large database of images from Hologic (Selenia and Selenia Dimensions), GE (Senographe and Senographe Essential), and Siemens (Mammomat Novation) digital breast x-ray systems).
4) Images in a database including BI-RADS category scores assigned by 15 readers were used to compare the reader BI-RADS scores to the q_abd, Q_abd, Vbd and Abd measures.

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

Conclusion:

The 510(k) Premarket Notification for Quantra contains adequate information and data to enable FDA/CDRH to determine substantial equivalence to the predicate device.

The submission contains the results of a hazard analysis and the "Level of Concern” for potential hazards has been classified as "Moderate”.