November 8, 2019

Qlarity Imaging, LLC
% Mr. Robert Tomek
Chief Technology Officer
222 W Merchandise Mart Plaza
Suite 1230
CHICAGO IL 60654

Re: K191959
Trade/Device Name: QuantX Breast MRI Biopsy Guidance Plugin
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 19, 2019
Received: October 16, 2019

Dear Mr. Tomek:

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,

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

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)*
K191959

Device Name
QuantX Breast MRI Biopsy Guidance Module

Indications for Use *(Describe)*
The QuantX Breast MRI Biopsy Guidance Plugin is a software application that assists users of the QuantX software device in planning MRI guided interventional procedures.

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."

Premarket Notification 510(k) Summary

1.1 Submitter

Manufacturer:	Qlarity Imaging, LLC
Address:	222 W Merchandise Mart Plaza #1230 Chicago, IL 60654
Contact Person:	Robert Tomek
Contact Person Title:	Chief Technology Officer
Telephone:	872.529.2239
Email:	rtomek@qlarityimaging.com

Date Prepared: August 28, 2019

1.2 Device Information

510(k) Submission type: Traditional

Device Trade Name: QuantX Breast MRI Biopsy Guidance Plugin

Device Common Name: Image Processing System

510(k) Submitter: Qlarity Imaging, LLC

Classification Regulation: 21 CFR 892.2050

Classification Regulation Name: Radiology

Regulatory Class: Class II

Classification Product Code: LLZ

1.3 Legally Marketed Predicate Device

The legally marketed predicate device is:

Device Name	Manufacturer Name	510(k) References	Product Code	Classification
DynaCAD	MRI Devices Corporation	K041286	LLZ	Class II

1.4 Device Description

The QuantX Breast MRI Biopsy Guidance Plugin assists users in planning MRI guided interventional procedures. Using information from MR images regarding the coordinates of a user-specified region of interest and fiducial coordinates, the software provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion.

Its primary goal is to identify where and how deep a biopsy needle should be inserted into an imaged breast in order to strike a targeted lesion or region of interest, as chosen by a trained medical professional.

The QuantX Breast MRI Biopsy Guidance Plugin may be used in either the SE or Advanced version of QuantX, a software program used for the display and analysis of medical images.

1.5 Indications for Use

The QuantX Breast MRI Biopsy Guidance Plugin is a software application that assists users of the QuantX software device in planning MRI guided interventional procedures.

1.6 Technological Characteristics

The QuantX Breast MRI Biopsy Guidance Plugin has the following same technological characteristics as the predicate device.

- User-initiated selection of target breast (left or right) and direction of approach (medial or lateral).
- Customized image display depending on side and direction of approach.
- User-initiated placement of fiducial marker and biopsy grid.
- User-initiated selection of needle size and block combination within the biopsy panel.
- Display of image overlay for fiducial marker and biopsy grid.
- Display of image overlay for target region of interest location and sample needle trajectory.
- Calculation and display of coordinates and depth to region of interest.

The following technological differences exist between the subject and predicate device; these differences do not affect the safety and effectiveness of the device when used as labeled:

- Subject device is a plugin that can be used in either the SE or Advanced versions of QuantX, a software program that analyzes patient breast images, and is designed to aid radiologists in the characterization of lesions as part of high-risk screening or diagnostic work-up. The predicate device is an image processing system designed to assist in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. Additionally, the predicate device assists users in planning MRI guided interventional procedures.

These differences do not affect the safety and effectiveness of the device when used as labeled.

1.7 NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEWS – as required by 807.92(b)(1)

The QuantX Breast MRI Biopsy Guidance Plugin has been successfully tested for its software requirements and features. Nonclinical tests included:

- Verification of proper activation of biopsy guidance mode and interface display;
- Verification of proper creation of needle block images;
- Verification of proper loading of image series to be used in biopsy guidance;
- Verification of complete and correct selection of grid type variables;
- Verification of complete and correct needle type variables;
- Verification of correct fiducial marker image-space coordinates;
- Verification of correct size of grid image overlay and location;
- Verification of correct lesion marker overlay display and image-space coordinates;
- Verification of proper display of selected breast, grid cell, and block hole;
- Verification of proper display of needle block image and needle depth;
- Verification of correct patient orientation indicators;
- Verification of lesion depth calculation by comparison to predicate;
- Verification of correct needle block hole by comparison to predicate;
- Verification of correct grid cell by comparison to predicate;
- Verification of guidance worksheet output;
- Validation testing demonstrates that the device conforms to user needs and intended use.

Based on these tests, we conclude that the subject device is safe and effective and substantially equivalent to the predicate device.

1.8 Conclusion

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.