DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Quantitative Insights, Inc.
% Mr. Robert Tomek
Chief Technology Officer
1452 E 53rd Street
CHICAGO IL 60615

May 17, 2017

Re: K170195
Trade/Device Name: QuantX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2017
Received: February 21, 2017

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. 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,

For

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170195

Device Name
QuantX

Indications for Use *(Describe)*
QuantX is a quantitative image analysis software device used to assist radiologists in the assessment and characterization of breast abnormalities using MR image data. The software automatically registers images, and segments and analyzes user-selected regions of interest (ROI). QuantX extracts image data from the ROI to provide volumetric and surface area analysis. These imaging features are then displayed to the user in a dedicated analysis panel on the display monitor.

When interpreted by a skilled physician, this device provides information that may be useful for screening and diagnosis. Patient management decisions should not be made based solely on the results of QuantX analysis.

QuantX may also be used as an image viewer of multi-modality digital images, including ultrasound and mammography. The software also includes tools that allow users to measure and document images, and output in a structured report.

Limitations: QuantX is not intended for primary interpretation of digital mammography images.

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.

PREMARKET NOTIFICATION 510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

Manufacturer:	Quantitative Insights, Inc.
Address:	1452 E. 53rd Street Chicago, IL 60615
Contact Person:	Robert Tomek
Contact Person Title:	Chief Technology Officer
Telephone:	872.529.2239
Email:	rtomek@quantinsights.com

Date Prepared: May 10, 2017

Device Information

Trade Name: QuantX
Common Name: Image Processing Software
Classfication Name: Picture archiving and communications system
Product Code: LLZ

A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate device is: CADStream Version 5 - K081556, K092954

B. DEVICE DESCRIPTION

QuantX is a software program that analyzes patient breast images, and is designed to aid radiologists in the characterization of lesions. After MR images are acquired from a third-party acquisition device, they can be loaded into the QuantX database manually, or automatically if connected to a DICOM-compatible device. Users then select and load the patient case to use the QuantX software tools in the examination of the images. Different types of MR sequences (T1, DCE, T2, DWI, etc.) can be viewed at the same time as mammography or ultrasound images from the same patient.

A variety of viewing tools are available to users. The MR images can be examined under different image planes (axial, sagittal, and coronal) as well as different image time points and slices. Users can use keyboard shortcuts or a scrolling mechanism to navigate through MR image slices. Colored axes serve as slice location markers for ease of pinpointing regions of interest (ROI). Images can be panned, changed in contrast, zoomed in or out, and measured. The Colormap feature visualizes contrast uptake (enhancement) studies, and a time intensity curve can be viewed for any location on the MR image.

QuantX includes image registration, and automated segmentation and analysis functions, based on a seed point indicated by the user. Users can select a ROI manually from the MR image, or use the automatic segmentation tool to obtain and accept a ROI, for input to the QuantX analytics.

The QuantX analytics display the QI Most Enhancing Curve, volume and surface area of the specified region. A user experienced with the significance of such data will be able to view and interpret this additional information during the diagnosis of breast lesions.

C. INDICATIONS FOR USE

QuantX is a quantitative image analysis software device used to assist radiologists in the assessment and characterization of breast abnormalities using MR image data. The software automatically registers images, and segments and analyzes user-selected regions of interest (ROI). QuantX extracts image data from the ROI to provide volumetric and surface area analysis. These imaging features are then displayed to the user in a dedicated analysis panel on the display monitor.

When interpreted by a skilled physician, this device provides information that may be useful for screening and diagnosis. Patient management decisions should not be made based solely on the results of QuantX analysis.

QuantX may also be used as an image viewer of multi-modality digital images, including ultrasound and mammography. The software also includes tools that allow users to measure and document images, and output in a structured report.

Limitations: QuantX is not intended for primary interpretation of digital mammography images.

An assessment has been made on the differences in indications between QuantX and the predicate device, and it has been determined that these changes do not raise any new questions regarding the safety and effectiveness of the device.

D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

QuantX has the following same technological characteristics as its predicate device. It is an MRI data post-processing software device, and is DICOM compatible. These similar features include:

- Visualization tools – standard 2D and 3D image viewing tools, MIPs, reformats
- Analysis – registration, subtractions, kinetic analysis, parametric image maps, apparent diffusion coefficient (ADC) maps, automatic and manual segmentation tools
- Standardized reporting tools incorporating user selected finding and assessment
- User interface and interaction tools that enhance workflow efficiency

- Communication and storage functions including DICOM standard interfaces

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 does not support coil inhomogeneity correction
- Subject does not support interventional planning
- Workflow efficiencies are implemented differently in the subject and predicate devices
- In addition to volume computation, the subject device includes a surface area computation which provides an additional indicator of lesion size

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

QuantX has been successfully tested for its software requirements and features.

Nonclinical tests included:

- Verification of the proper loading, display, and manipulation of MR image data.
- Verification of the proper loading, display, and manipulation of Mammographic and Ultrasound image data.
- Verification that the calculation and display of kinetic colormaps were accurate on MR image data.
- Verification testing of lesion segmentation on MR image data.
- Verification that all measurements and BIRADS reporting were recorded correctly.
- Validation testing demonstrates the device conforms to user needs and intended use.

F. CONCLUSION

QuantX provides features to aid radiologists in the visualization and analysis of breast MR images. The potential hazards, including risk analysis and design considerations, have been examined and incorporated into the software development process.

This 510(k) Premarket Notification provides adequate information to establish substantial equivalence to the predicate device.