



Food and Drug Administration
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Silver Spring, MD 20993-0002

Quantitative Insights, Inc
Robert Tomek
Chief Technology Officer
1452 E 53rd St
Chicago, Illinois 60615

July 19, 2017

Re: DEN170022

Trade/Device Name: QuantX

Regulation Number: 21 CFR 892.2060

Regulation Name: Radiological computer-assisted diagnostic (CADx) software for lesions
suspicious for cancer

Regulatory Class: Class II

Product Code: POK

Dated: April 7, 2017

Received: April 7, 2017

Dear Robert Tomek:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the QuantX, a prescription device under 21 CFR Part 801.109 with the following indications for use:

QuantX is a computer-aided diagnosis (CADx) 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 analysis and computer analytics based on morphological and enhancement characteristics. These imaging (or radiomic) features are then synthesized by an artificial intelligence algorithm into a single value, the QI score, which is analyzed relative to a database of reference abnormalities with known ground truth.

QuantX is indicated for evaluation of patients presenting for high-risk screening, diagnostic imaging workup, or evaluation of extent of known disease. Extent of known disease refers to both the assessment of the boundary of a particular abnormality as well as the assessment of the total disease burden in a particular patient. In cases where multiple abnormalities are present, QuantX can be used to assess each abnormality independently.

This device provides information that may be useful in the characterization of breast abnormalities during image interpretation. For the QI score and component radiomic

features, the QuantX device provides comparative analysis to lesions with known outcomes using an image atlas and histogram display format.

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.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into Class II. This order, therefore, classifies the QuantX, and substantially equivalent devices of this generic type, into Class II under the generic name “Radiological computer-assisted diagnostic (CADx) software for lesions suspicious for cancer.”

FDA identifies this generic type of device as: **Radiological computer-assisted diagnostic (CADx) software for lesions suspicious for cancer.**

A radiological computer-assisted diagnostic (CADx) software for lesions suspicious for cancer is an image processing device intended to aid in the characterization of lesions as suspicious for cancer identified on acquired medical images such as magnetic resonance, mammography, radiography, or computed tomography. The device characterizes lesions based on features or information extracted from the images and provides information about the lesion(s) to the user. Diagnostic and patient management decisions are made by the clinical user.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On April 7, 2017, FDA received your *de novo* requesting classification of the QuantX. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the QuantX into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the *de novo* request, FDA has determined that the QuantX indicated for use as follows:

QuantX is a computer-aided diagnosis (CADx) 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 analysis and computer analytics based on morphological and enhancement characteristics. These imaging (or radiomic) features are then synthesized by an artificial intelligence algorithm into a single value, the QI score, which is analyzed relative to a database of reference abnormalities with known ground truth.

QuantX is indicated for evaluation of patients presenting for high-risk screening, diagnostic imaging workup, or evaluation of extent of known disease. Extent of known disease refers to both the assessment of the boundary of a particular abnormality as well as the assessment of the total disease burden in a particular patient. In cases where multiple abnormalities are present, QuantX can be used to assess each abnormality independently.

This device provides information that may be useful in the characterization of breast abnormalities during image interpretation. For the QI score and component radiomic features, the QuantX device provides comparative analysis to lesions with known outcomes using an image atlas and histogram display format.

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.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and identified mitigations associated with the device type are summarized in the following table:

Identified Risks to Health	Identified Mitigations
Incorrect lesion(s) characterization leading to false positive results may result in incorrect patient management with possible adverse effects such as unnecessary treatment, unnecessary additional medical imaging and/or unnecessary additional diagnostic workup such as biopsy.	General Controls and Special Controls (1) and (2)
Incorrect lesion(s) characterization leading to false negative results may lead to complications, including incorrect diagnosis and delay in disease management.	General Controls and Special Controls (1) and (2)
The device could be misused to analyze images from an unintended patient population or on images acquired with incompatible imaging hardware or	General Controls and Special Controls (1) and (2)

incompatible image acquisition parameters, leading to inappropriate diagnostic information being displayed to the user.	
Device failure could lead to the absence of results, delay of results or incorrect results, which could likewise lead to inaccurate patient assessment.	General Controls and Special Controls (1) and (2)

In combination with the general controls of the FD&C Act, the radiological computer-assisted diagnostic (CADx) software for lesions suspicious for cancer is subject to the following special controls:

1. Premarket notification submission must include:

- i. A detailed description of the image analysis algorithms including, but not limited to, a detailed description of the algorithm inputs and outputs, each major component or block, and algorithm limitations.
- ii. A detailed description of pre-specified performance testing protocols and dataset(s) used to assess whether the device will improve reader performance as intended.
- iii. Results from performance testing protocols that demonstrate that the device improves reader performance in the intended use population when used in accordance with the instructions for use. The performance assessment must be based on appropriate diagnostic accuracy measures (e.g., receiver operator characteristic plot, sensitivity, specificity, predictive value, and diagnostic likelihood ratio). The test dataset must contain a sufficient number of cases from important cohorts (e.g., subsets defined by clinically relevant confounders, effect modifiers, concomitant diseases, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and imaging equipment.
- iv. Standalone performance testing protocols and results of the device.
- v. Appropriate software documentation (e.g., device hazard analysis; software requirements specification document; software design specification document; traceability analysis; description of verification and validation activities including system level test protocol, pass/fail criteria, results, and cybersecurity).

2. Labeling must include:

- i. A detailed description of the patient population for which the device is indicated for use.
- ii. A detailed description of the intended reading protocol.
- iii. A detailed description of the intended user and recommended user training.
- iv. A detailed description of the device inputs and outputs.
- v. A detailed description of compatible imaging hardware and imaging protocols.
- vi. Warnings, precautions, and limitations, including situations in which the device may fail or may not operate at its expected performance level (e.g., poor image quality or for certain subpopulations), as applicable.
- vii. Detailed instructions for use.
- viii. A detailed summary of the performance testing, including: test methods, dataset characteristics, results, and a summary of sub-analyses on case distributions stratified by

relevant confounders (e.g., lesion and organ characteristics, disease stages, and imaging equipment).

In addition, this is a prescription device and must comply with 21 CFR 801.109.

This device is subject to the premarket notification requirements under section 510(k) of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the radiological computer-assisted diagnostic (CADx) software for lesions suspicious for cancer they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning the contents of the letter, please contact Daniel Krainak at 301-796-0478 or 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>.

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health