AIQ Solutions, Inc.
℅ Mr. Mitch Lewandowski
Principal/Consultant
EpiReg LLC
3428 John Muir Drive
MIDDLETON WI 53562

July 23rd, 2018

Re: K173444
Trade/Device Name: Quantitative Total Extensible Imaging (QTxI)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 8, 2018
Received: June 12, 2018

Dear Mr. Lewandowski:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Digitally signed by Jeffrey J. Ballyns -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000569725, cn=Jeffrey J. Ballyns -S
Date: 2018.07.23 10:41:24 -04'00'

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)*
K173444

Device Name
Quantitative Total Extensible Imaging (QTxI)

Indications for Use *(Describe)*
Quantitative Total Extensible Imaging (QTxI) is a software tool used to aid in evaluation and information management of digital medical images by trained medical professionals including, but not limited to, radiologists, oncologists, nuclear medicine physicians, medical imaging technologists, dosimetrists and physicists. The medical modalities of these medical images include DICOM CT and PET as supported by ACR/NEMA DICOM 3.0.

QTxI assists in the following indications:
• Receive, store, retrieve, display and process digital medical images.
• Create, display and print reports from those images.
• Provide medical professionals with the ability to display, register, and fuse medical images.
• Identify Regions of Interest (ROIs) and perform ROI contouring allowing quantitative/statistical analysis of full or partial body scans.
• Evaluate quantitative change in ROIs (total or partial body; individual ROI within individual) with 3D interactive rendering of images with highlighted ROIs.

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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510(k) Summary

1. 510(k) Owner:

AIQ Solutions Inc.

2. Address:

8025 Excelsior Drive
Madison, WI 53717

3. Contact Person:

Mitch Lewandowski, M.S./ M.P.H; Principal Consultant
Email: info@epireg.com
Tel: 608 712-8585
Direct: 608 695-9333

4. Date 510(k) Summary Prepared:

05 October 2017

5. Trade Name:

Quantitative Total Extensible Imaging (QTxI) Medical Image and Information Management System

6. Common Name:

Picture archiving and communication system

7. Classification Name:

21 CFR 892.2050, Picture archiving and communication system (LLZ)

8. Predicate Device(s):

Exini Diagnostics AB; EXINI, K122205

9. Device Description:

Quantitative Total Extensible Imaging (QTxI) is a software tool designed for use in medical imaging. It is stand-alone software which operates on Windows 7 and Windows 10. Its intended function and use is to provide medical professionals with the means to display, register and fuse medical images from multiple modalities including DICOM PET and CT. Additionally, it identifies Regions of Interest (ROIs) and performs ROI contouring allowing quantitative/statistical analysis of full or partial-body scans through registration to template space.

QTxI is designed to support multiple image analysis modules. Each module is designed for a specific image analysis purpose. Currently QTxI includes only the Quantitative Total Bone Imaging (QTBI) module, which is designed to identify and measure hot-spots on PET scans. QTBI aids the efficiency of medical professionals through automatic quantification of ROIs and changes in those

ROIs, including 3D interactive rendering of the patient skeleton with highlighted Regions of Interest.

QTxI also functions as a Picture Archive and Communications System (PACS) intended to receive, store, retrieve, display and process digital medical images, as well as create, display and print reports from those images. It also provides platform features for security, workflow and integration.

10. Indications for Use and Intended Use

Quantitative Total Extensible Imaging (QTxI) is a software tool used to aid in evaluation and information management of digital medical images by trained medical professionals including, but not limited to, radiologists, oncologists, nuclear medicine physicians, medical imaging technologists, dosimetrists and physicists. The medical modalities of these medical images include DICOM CT and PET as supported by ACR/NEMA DICOM 3.0.

QTxI assists in the following indications:

- Receive, store, retrieve, display and process digital medical images.
- Create, display and print reports from those images.
- Provide medical professionals with the ability to display, register, and fuse medical images.
- Identify Regions of Interest (ROIs) and perform ROI contouring allowing quantitative/statistical analysis of full or partial body scans.
- Evaluate quantitative change in ROIs (total or partial body; individual ROI within individual) with 3D interactive rendering of images with highlighted ROIs.

11. Technological Characteristics

QTxI has substantially equivalent indications for use, principle of operation, and technological characteristics as the Exini Diagnostics AB; EXINI, K122205.

The following table summarizes and compares data on the Exini Diagnostics AB; EXINI, K122205, and supporting predicate device MIMvista Corp. MIM4.1 (Seastar), K071964.

Specification / Characteristic	**Quantitative Total Extensible Imaging (QTxI)** ***Subject Device***	**Exini Diagnostics AB; EXINI, K122205** ***Predicate Device***	**MIMvista Corp. MIM4.1 (Seastar), K071964** ***Supporting Predicate Device***	**Comparison to Predicate(s)**
Product Code	LLZ	LLZ	LLZ	No difference
Regulation Number	892.2050	892.2050	892.2050	No difference
Regulatory Class	II	II	II	No difference
Review Panel	Radiology	Radiology	Radiology	No difference
Predicate Device	Exini Diagnostics AB; EXINI (K122205)	MEQIA, IBIS Explorer and Markup Software (K111319)	MIM4.0 (K060816); IKOEngelo (K061006); Centricity PACS (K043415)	N/A
510(k)/ Type	K173444, Traditional	K122205, Traditional	K071964, Traditional	No difference
Features	Receive, store, retrieve, display and process digital medical images, as well as create, display and print reports from those images	Software tool set for acceptance, transfer, storage, image display, manipulation and quantification of digital medical images.	Receive, transmit, store, retrieve, display, print and process digital medical images, as well as create, display and print reports from those images	No difference
Medical Modalities	DICOM CT and PET as supported by ACR/NEMA DICOM 3.0	Nuclear imaging (NM) and computed tomography (CT) as supported by DICOM 3.0 standard.	CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0.	QTxI does not utilize as many medical modalities as predicate, but does utilize equivalent modalities in those used by both systems.
Operating System	Window 7 or Windows 10	Microsoft Windows operating system	Windows 2000/XP	QTxI uses newer versions of MicroSoft Windows software
Methodology	Identifies Regions of Interest (ROI) and performs ROI contouring allowing quantitative/statistical analysis of full or partial-body scans through registration to template space	The device uses image processing techniques for segmentation of skeletal regions, normalization and hotspot contouring/ segmentation. This device is semi-automatic in that it requires a manual step (hotspot verification step) where the user reviews and edits the selection of hotspots that are used as input for quantitative analysis. The device performs quantitative analysis based on 2D ROI (regions of interests) measurements in whole body bone scans.	Generates contours using a deformable registration technique which registers pre-contoured patients to target patients. Registrations are either between a serial pair of intra-patient volumes or between a pre-existing atlas of contoured patients and a patient volume	All devices perform centering analyses utilizing a template model. QTxI also registers regions of the patient.

Specification / Characteristic	**Quantitative Total Extensible Imaging (QTxI)** ***Subject Device***	**Exini Diagnostics AB; EXINI, K122205** ***Predicate Device***	**MIMvista Corp. MIM4.1 (Seastar), K071964** ***Supporting Predicate Device***	**Comparison to Predicate(s)**
Indications for Use	Quantitative Total Extensible Imaging (QTxI) is a software tool used to aid in evaluation and information management of digital medical images by trained medical professionals including, but not limited to, radiologists, oncologists, nuclear medicine physicians, medical imaging technologists, dosimetrists and physicists. The medical modalities of these medical images include DICOM CT and PET as supported by ACR/NEMA DICOM 3.0. QTxI assists in the following indications: • Receive, store, retrieve, display and process digital medical images • Create, display and print reports from those images • Provide medical professionals with the ability to display, register, and fuse medical images	EXINI is intended to be used by trained healthcare professionals and researchers for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital medical images. The system is intended to be used with images acquired using nuclear imaging (NM) and computed tomography (CT). The software provides general Picture Archiving and Communications System (PACS) tools and a clinical application for oncology including lesion marking and analysis.	MIM 4.1 (SEASTAR) software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 4.1 (SEASTAR) assists in the following indications: • Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects. • Create, display and print reports from medical images. • Registration, fusion display, and review of medical images for diagnosis, treatment, evaluation, and treatment planning. • Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.	All systems are used to receive, store, retrieve, display, and process medical images and DICOM objects. This is accomplished via registration to a template space and subsequent analysis of the image data. The predicate device has multiple uses in the therapeutic space, which is not specific to any device.

Specification / Characteristic	**Quantitative Total Extensible Imaging (QTxI)** ***Subject Device***	**Exini Diagnostics AB; EXINI, K122205** ***Predicate Device***	**MIMvista Corp. MIM4.1 (Seastar), K071964** ***Supporting Predicate Device***	**Comparison to Predicate(s)**
Indications for Use (continued)	• Identify Regions of Interest (ROIs) and perform ROI contouring allowing quantitative/ statistical analysis of full or partial body scans • Evaluate quantitative change in ROIs (total or partial body; individual ROI within individual) with 3D interactive rendering of images with highlighted ROIs.		• Localization and definition of objects such as tumors and normal tissues in medical images. • Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management • Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.	

12. Performance Data (Nonclinical)

QTxI is a software tool. Non-clinical performance bench tests and simulated clinical performance tests have been performed on the Quantitative Total Extensible Imaging (QTxI) in order to verify the device characteristics. Testing conducted to demonstrate substantial equivalence included:

- Software verification testing that demonstrates the device meets product performance and functional specifications.

- Software verification testing demonstrating that DICOM information collected with medical imaging systems and transmitted through manual or virtual input are captured, transmitted, and stored properly to maintain data integrity (e.g., no loss of data).

13. Conclusion

QTxI met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, and test protocols.

The Quantitative Total Extensible Imaging (QTxI) software tool is substantially equivalent with respect to product performance, indications for use, intended use, scientific principles, technological characteristics, and materials, as the predicate device, Exini Diagnostics AB; EXINI, K122205.