Quantitative Radiology Solutions, LLC
% Mary Vater
510(k) Consultant
Medical Device Academy
345 Lincoln Hill Rd.
SHREWSBURY, VT 05738

April 20, 2021

Re: K203610
Trade/Device Name: Automatic Anatomy Recognition (AAR)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: QKB
Dated: March 22, 2021
Received: March 23, 2021

Dear Mary Vater:

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,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203610

Device Name
Automatic Anatomy Recognition System

Indications for Use *(Describe)*

Automatic Anatomy Recognition (AAR) is a software-only medical device intended for use by technicians and trained physicians to derive contours of anatomical structures from computed tomography studies for input to a radiation treatment planning system. It is only intended to work for anatomical structures in the head & neck and thoracic body regions. It is not for use on patients below 18 years of age and it relies on third party treatment planning systems to display and edit the contours.

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.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Quantitative Radiology Solutions, LLC
3675 Market Street, Suite 200
Philadelphia, PA 19104 | USA
Tel: +1.973.590.8574

Contact Person: Steve Owens
Date Prepared: December 9, 2020

II. DEVICE

Name of Device:	Automatic Anatomy Recognition
Classification Name:	Picture Archiving And Communications System
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Product Classification Code:	QKB

III. PREDICATE DEVICE

Predicate Manufacturer:	Xiamen Manteia Technology LTD.
Predicate Trade Name:	AccuContour™
Predicate 510(k):	K191928

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Automatic Anatomy Recognition product for radiation therapy planning (AAR) is a software-only medical device and is deployed on a cloud-based platform. AAR is intended to be used on adults undergoing treatment that requires the identification of anatomical structures in the body considered to be "organs at risk" (OAR). AAR is intended to be used in the head and neck and thoracic body regions.

AAR operates independently from the treatment plan that is subsequently created based on AAR-generated contours. Therefore, AAR is agnostic to the method of radiation treatment delivery such as photons, protons, or other, to the modality of radiation treatment such as three-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), or other, and to the intent of radiation treatment such as definitive (curative), neoadjuvant, adjuvant, or palliative.

AAR is also agnostic to the disease process being treated in the head and neck or thoracic body regions. For example, the identification of OARs is required during the treatment of head and neck cancers such as squamous cell carcinoma, brain cancer, and lymphoma. The identification of OARs is also required during the treatment of thoracic cancers such as lung cancer, breast cancer, esophageal cancer, lymphoma, and thymoma, just to name a few.

AAR automatically processes computed tomography (CT) studies and produces contours with no human intervention. AAR does not provide the capability to modify contours. If adjustments are required, they must be performed on another system.

V. INDICATIONS FOR USE

Automatic Anatomy Recognition (AAR) is a software-only medical device intended for use by technicians and trained physicians to derive contours of anatomical structures from computed tomography studies for input to a radiation treatment planning system. It is only intended to work for anatomical structures in the head & neck and thoracic body regions. It is not for use on patients below 18 years of age and it relies on third party treatment planning systems to display and edit the contours.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have identical indications for use.
- Materials – The predicate and subject device are both software-only medical devices.
- Design – The predicate and subject device both utilize deep learning contouring to automatically contour the organ-at-risk for the head, neck, and thorax.
- Energy Source – The predicate and subject device both run within the users' existing computer system.
- Other Design Features – The predicate device has additional features such as patient management, review of processed images, automatic image registration, manual contouring functionality, and segmentation in the abdomen and pelvic regions. This additional functionality is not required to achieve the intended use for the subject device.
- Performance Testing – The predicate and subject device conducted segmentation performance tests to evaluate the automated segmentation accuracy using DICE similarity coefficients. These tests were further supported by additional tests using a mean 95% Hausdorff Distance (HD) calculation.

Table 1: Proposed Predicate Device

	Subject Device	Proposed Predicate Device	Rationale for SE
Device Name	Automatic Anatomy Recognition (AAR)	AccuContour™	N/A
Applicant	Quantitative Radiology Solutions	Xiamen Manteia Technology LTD.	N/A
510(k) Number	TBD	K191928	N/A
Decision Date	TBD	02/28/2020	N/A
Regulation Number	892.2050	892.2050	Same
Regulation Name	Picture archiving and communication system	Picture archiving and communication system	Same
Device	Radiological Image Processing Software for Radiation Therapy	Radiological Image Processing Software for Radiation Therapy	Same
Regulatory Definition	To provide semi-automatic-or fully-automated radiological image process and analysis tools for radiation therapy. Software implementing artificial intelligence (AI) including non-adaptive machine learning algorithms trained with clinical and/or artificial radiological images. In these devices, the algorithm training images typically impact device	To provide semi-automatic or fully-automated radiological image process and analysis tools for radiation therapy. Software implementing artificial intelligence (AI) including non-adaptive machine learning algorithms trained with clinical and/or artificial radiological images. In these devices, the algorithm training images typically impact device performance. AI based	Both the subject device and the predicate fall under the regulatory definition for 892.2050, product code QKB.

	performance. AI based radiological image processing software is intended to be used in the workflow of radiation therapy. Adaptive AI algorithms are not within the scope of this product code. Primary radiation dose calculation or plan optimization for treatment planning are not within scope of the product code.	radiological image processing software is intended to be used in the workflow of radiation therapy. Adaptive AI algorithms are not within the scope of this product code. Primary radiation dose calculation or plan optimization for treatment planning are not within scope of the product code.	
Product Code	QKB	QKB	Same
Classification	Class II	Class II	Same
510(k) Review Panel	Radiology	Radiology	Same
Combination Product?	No	No	Same
Rx or OTC?	RX	RX	Same
Intended Use / Indications for Use	Automatic Anatomy Recognition (AAR) is a software-only medical device intended for use by technicians and trained physicians to derive contours of anatomical structures from computed tomography studies for input to a radiation treatment planning system. It is only intended to work for anatomical structures in the head & neck and thoracic body regions. It is not for use on patients below 18 years of age and it relies on third party treatment planning systems to display and edit the contours.	It is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treating planning, treatment evaluation and treatment adaptation.	Same
Image process functions	1) Deep learning contouring: it can automatically contour anatomical structures, including head and neck, thorax (for both male and female).	1) Deep learning contouring: it can automatically contour the organ-at-risk, including head and neck, thorax, abdomen and pelvis (for both male and female); 2) Automatic Registration, and 3) Manual Contour	Same. AAR contains only Deep Learning contouring
General Functionalities	● Receive, add/edit/delete, transmit, input/export, medical images and DICOM data	● Receive, add/edit/delete, transmit, input/export, medical images and DICOM data; ● Patient management; ● Review of processed images; ● Open and Save of files.	Same. AAR only receives, adds/edits/deletes, transmits, inputs/exports medical images and DICOM data
Operating Systems	Linux	Windows	QRS utilizes Linux as this OS is more secure as compared to Windows
Segmentation Features			
Algorithm	Deep Learning	Deep Learning	Same
Compatible Modality	Non-Contrast CT	Non-Contrast CT	Same

Compatible Scanner Models	No limitation on scanner model, DICOM 3.0 compliance required	No limitation on scanner model, DICOM 3.0 compliance required	Same
Compatible Treatment Planning System	No limitation on TPS model, DICOM 3.0 compliance required.	No limitation on TPS model, DICOM 3.0 compliance required.	Same
Contraindications	AAR is not intended for use on patients below 18 years of age;	None	AAR is intended for use in adults
Segmentation Features			
Performance Testing	• Segmentation Performance Test Evaluated automated segmentation accuracy non-inferiority using DICE similarity coefficients. • Software Verification and Validation testing	• Segmentation Performance Test Evaluated automated segmentation accuracy non-inferiority using DICE similarity coefficients. • Registration Performance Test	Segmentation Performance Testing is equivalent. Registration performance test is N/A because the subject device does not do registration.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life Testing

Not Applicable (Standalone Software)

Biocompatibility Testing

Not Applicable (Standalone Software)

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable (Passive Device)

Software Verification and Validation Testing

Software Verification and Validation Testing included testing at the unit, integration, and system level per IEC 62304 standard.

Mechanical and acoustic Testing

Not Applicable (Standalone Software)

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.