Quanta Computer Inc.
% Joe Wang, Research Specialist
No. 188, Wenhua 2nd Rd
Guishan Dist.
Taoyuan City, 33383
TAIWAN

February 13, 2024

Re: K231855
Trade/Device Name: QOCA® image Smart RT Contouring System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: January 8, 2024
Received: January 8, 2024

Dear Joe Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming

product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*
K231855

Device Name
QOCA® image Smart RT Contouring System

Indications for Use *(Describe)*
QOCA® image Smart RT Contouring System is a post-processing software intended to automatically contour DICOM CT imaging data using deep-learning-based algorithms.
Contours that are generated by QOCA® image Smart RT Contouring System may be used as input for clinical workflows including external beam radiation therapy treatment planning. QOCA® image Smart RT Contouring System must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by QOCA® image Smart RT Contouring System.
The output of QOCA® image Smart RT Contouring System in the format of RTSTRUCT objects are intended to be used by radiation oncology department.
QOCA® image Smart RT Contouring System does not provide a user interface for data visualization. System settings, user settings, progress status, and other functionalities are managed via a web-based interface.
The software is not intended to automatically detect or contour lesions. Only DICOM images of adult patients are considered to be valid input.

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

5.1. Type of Submission: Traditional

5.2. Date of Summary: 01/08/2024

5.3. Submitter: Quanta Computer Inc.

Address: No. 188, Wenhua 2nd Rd., Guishan Dist. Taoyuan City 33383, Taiwan (R.O.C)
Phone: +886-3-327-2345
Contact: Joe Wang
joe_wang@quantatw.com

5.4. Identification of the Device:

Proprietary/Trade Name:	QOCA® image Smart RT Contouring System
Model Number:	ZSWR901
Review Panel:	Radiology
Regulation Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR 892.2050
Product Code:	QKB
Device Class:	II

5.5. Identification of the Predicate Device:

Predicate Device Name:	AccuContour™
Model Number:	--
510(k) Number:	K191928
Manufacturer:	Xiamen Manteia Technology LTD.
Regulation Number:	21 CFR 892.2050
Product Code:	QKB
Device Class:	II

5.6. Intended Use/Indications for Use of the Device

QOCA® image Smart RT Contouring System is a post-processing software intended to automatically contour DICOM CT imaging data using deep-learning-based algorithms.
Contours that are generated by QOCA® image Smart RT Contouring System may be used as input for clinical workflows including external beam radiation therapy treatment planning. QOCA® image Smart RT Contouring System must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by QOCA® image Smart RT Contouring System.
The output of QOCA® image Smart RT Contouring System in the format of RTSTRUCT objects are intended to be used by radiation oncology department.
QOCA® image Smart RT Contouring System does not provide a user interface for data visualization. System settings, user settings, progress status, and other functionalities are managed via a web-based interface.
The software is not intended to automatically detect or contour lesions. Only DICOM images of adult patients are considered to be valid input.

5.7. Device Description

QOCA® image Smart RT Contouring System is a post-processing software used to automatically contour DICOM CT imaging data using deep-learning-based algorithms. QOCA® image Smart RT Contouring System contouring workflow supports CT input data and produces RTSTRUCT outputs. Contours that are generated by QOCA® image Smart RT Contouring System may be used as input for clinical workflows including external beam radiation therapy treatment planning.

The output of QOCA® image Smart RT Contouring System, in the form of RTSTRUCT objects, are intended to be used by radiation oncology department. The output of QOCA® image Smart RT Contouring System must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by QOCA® image Smart RT Contouring System.

QOCA® image Smart RT Contouring System includes the following functionality:

- Automated contouring of organs at risk (OAR) workflow
  - Input - DICOM CT
  - Output - DICOM CT (Original), DICOM RTSTRUCT

- Web-based interface of system settings, user settings, and checking progress status

QOCA® image Smart RT Contouring System is intended to be used on adults undergoing treatment that requires the identification of anatomical structures in the body considered to be OAR. QOCA® image Smart RT Contouring System is intended to be used in the head, neck, and pelvis regions.

5.8. Comparison of Technological Characteristics with the Predicate Device

QOCA® image Smart RT Contouring System submitted in this 510(k) file is substantially equivalent in intended use, safety and performance to the cleared AccuContour™ (K191928). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject Device	Predicate Device	Substantial Equivalence Determination
510(k) Number	K231855	K191928	--
Proprietary Name	QOCA® image Smart RT Contouring System	AccuContour™	--
Manufacturer	Quanta Computer Inc.	Xiamen Manteia Technology LTD.	--
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	***Same***
Product Code	QKB	QKB	***Same***
Classification	Class II	Class II	***Same***
Intended Use/Indication for Use	QOCA® image Smart RT Contouring System is a post-processing software intended to automatically contour DICOM CT imaging data using deep-learning-based algorithms.	It is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information	***Similar*** Both devices utilize artificial intelligence algorithms to automatically contour organs at risk, including the head and neck, as well as the pelvis,

	Contours that are generated by QOCA® image Smart RT Contouring System may be used as input for clinical workflows including external beam radiation therapy treatment planning. QOCA® image Smart RT Contouring System must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by QOCA® image Smart RT Contouring System. The output of QOCA® image Smart RT Contouring System in the format of RTSTRUCT objects are intended to be used by radiation oncology department. QOCA® image Smart RT Contouring System does not	for treatment planning, treatment evaluation and treatment adaptation.	for radiation treatment planning.

	provide a user interface for data visualization. System settings, user settings, progress status, and other functionalities are managed via a web-based interface. The software is not intended to automatically detect or contour lesions. Only DICOM images of adult patients are considered to be valid input.		
Operating System	Windows	Windows	***Same***
Algorithm	Deep Learning	Deep Learning	***Same***
Segmentation of Organ at Risk in the Anatomic Regions	Brain stem, Esophagus, Mandible, Pharyngeal, Constrictor Muscle (PCM), Spinal cord, Thyroid, Right eye, Light eye, Right lens, Left lens, Right optic nerve, Left optic nerve, Right parotid, Left parotid, Anorectum, Bladder, Bowel bag, Lumbar spine L5, Bilateral seminal vesicles, Right iliac, Left iliac, Right proximal femur,	Head and Neck, Thorax, Abdomen, and Pelvis	***Similar*** The subject device contains head and neck, and pelvis.

	Left proximal femur		
Compatible Modality	CT Images	Non-Contrast CT Images	***Similar*** The subject device and the predicate device are both compatible only with CT images for the segmentation feature. The predicate device claims to handle only non-contrast CT images, while the subject device can be used with both contrast and non-contrast CT images.
Compatible Scanner Models	No specific requirement for the scanner model, it is recommended to use multi-detector CT (MDCT) equipment with more than 16 slices for Radiation Therapy Simulation CT, and DICOM compliance required.	No Limitation on scanner model, DICOM 3.0 compliance required.	***Similar*** The Subject Device and Predicate Device are substantially equivalent in their requirements for DICOM compliance, ensuring interoperability and standardization in medical imaging data. The Subject Device recommends a multi-detector CT

			scanner with more than 16 slices specifically for Radiation Therapy Simulation CT to provide detailed imaging necessary for accurate therapy planning.
Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM 3.0compliance required.	***Same***
Contraindications	Adult use only.	There are no known specific situations that contraindicate the use of this device.	***Similar*** The subject device is designed for adult use, and there are no known specific situations that contraindicate its usage.
Segmentation Performance	The segmentation performance was validated using private datasets from Taiwan and public datasets was collected from various sources, including the USA. The datasets were obtained from major vendors such as GE, Siemens, Philips, and TOSHIBA. The	The segmentation performance was validated using datasets from China and the USA using three major vendors (GE, Siemens and Philips). The segmentation accuracy is evaluated using DICE similarity	***Same***

	accuracy of the segmentation was evaluated using the DICE similarity coefficient (DSC).	coefficient (DSC).	

Similarity and Difference

The subject device has the similar intended use and features to the predicate device. Both devices are intended to aid user to contour the organ-at-risk (OAR) by artificial intelligence algorithm. And they are not intended to be used on a stand-alone basis for clinical decision-making or clinical diagnosis.

The primary difference between the subject and predicate devices lies in their "Compatibility with Scanner Models" and "Imaging Modalities". However, the subject device's approach to presenting results aligns with that of the predicate device. Furthermore, both devices meet the requirements for DICOM compliance, ensuring interoperability and standardization in medical imaging data. Notably, the subject device recommends the use of a multi-detector CT scanner with more than 16 slices for radiation therapy simulation CT, enabling detailed imaging essential for precise therapy planning. Both devices exclusively support CT images for the segmentation feature. While the predicate device is limited to non-contrast CT images, the subject device can handle both contrast and non-contrast CT images. Therefore, it will not affect the substantial equivalence.

5.9. Performance Data

The subject device, QOCA® image Smart RT Contouring System has been evaluated and verified in accordance with software specifications and applicable performance standards to ensure performance.

The subject device has undergone software validation activities in accordance with *IEC 62304: 2006/A1:2016 - Medical device software - Software life cycle processes*, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, *Content of Premarket submissions for Devices Software Functions* and *Content of Premarket Submission for Management of Cybersecurity in Medical Devices*.

The performance of the subject device has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification

and validation testing.

Nonclinical Tests

During the development of the model, CT images had retrospectively collected from 2000 to 2021 from two hospitals in Taiwan, comprising a total of 317 cases of head and neck images and 351 cases of pelvic images. These images were distributed in an 8:1:1 ratio into Training datasets, Validation datasets, and Test datasets.

In the Test datasets, an additional 38 cases from United States public datasets (The Cancer Imaging Archive (TCIA), and Gold Atlas - Male Pelvis (GA)) were included to ensure that the intended patient population in the United States could achieve the expected purpose.

The CT images come from the following equipment:

- GE Discovery CT590 RT
- GE Discovery STE
- GE Discovery ST
- SIEMENS SOMATOM PLUS 4
- SIEMENS Sensation 64
- PHILIPS Brilliance Big Bore
- TOSHIBA Aquilion ONE
- TOSHIBA Aquilion/LB

Segmentation Performance Test

The standalone performance of the subject device has been validated in a retrospective performance study on CT data previously acquired for RT treatment planning.

Data collection included 110 head and neck CT images and 110 pelvis CT images, with each anatomical site contributing 50 cases from Taiwan and 60 cases from the United States public dataset, TCIA. These 220 cases are independent of the data used in nonclinical tests and have not been reused. The demographic distribution of this data is as follows:

- Gender: 97 Female (55 Head and Neck; 42 Pelvis), 123 Male (55 Head and Neck; 68 Pelvis).
- Age: Adult (above 22 years old).
- Ethnicity: Data collected from the United States and Taiwan.
- Equipment:
  - GE Discovery ST

- GE MEDICAL SYSTEMS LightSpeed Plus
- SIEMENS Sensation Open
- PHILIPS Brilliance Big Bore
- PHILIPS GEMINI TF Big Bore
- TOSHIBA Aquilion ONE

Ground truth annotations were established following *CT-based delineation of organs at risk in the head and neck region: DAHANCA, EORTC, GORTEC, HKNPCSG, NCIC CTG, NCRI, NRG Oncology and TROG consensus guidelines* and *Pelvic Normal Tissue Contouring Guidelines for Radiation Therapy: A Radiation Therapy Oncology Group Consensus Panel Atlas*.

The results for standalone performance testing are as follows:

Body Part	OARs	Acceptance Criteria (*DSC*)	Model Performance	
			DSC	*HD95*
Head and Neck	Brain stem	0.87	0.942 (±0.0215)	4.173 (±20.9737)
	Esophagus	0.76	0.875 (±0.0859)	4.694 (±5.5237)
	Mandible	0.93	0.956 (±0.0167)	1.413 (±0.9036)
	Pharyngeal constrictor muscle	0.70	0.820 (±0.0692)	2.232 (±1.3013)
	Spinal cord	0.87	0.931 (±0.0282)	2.330 (±3.3562)
	Thyroid	0.83	0.873 (±0.1756)	3.249 (±5.7852)
	Right eye	0.91	0.956 (±0.0149)	2.038 (±0.9599)
	Left lens	0.80	0.876 (±0.1150)	1.526 (±1.0436)
	Left optic nerve	0.66	0.805 (±0.0849)	3.548 (±3.0927)
	Right parotid	0.86	0.924 (±0.0303)	3.825 (±2.7730)

Body Part	OARs	Acceptance Criteria (*DSC*)	Model Performance	
			DSC	*HD95*
Pelvis	Anorectum	0.70	0.929 (±0.0755)	7.929 (±14.2608)
	Bladder	0.82	0.959 (±0.0912)	4.402 (±9.7696)
	Bowel bag	0.70	0.944 (±0.0338)	11.237 (±8.5063)
	Lumbar spine L5	0.90	0.960 (±0.0648)	5.985 (±31.2018)
	Bilateral seminal vesicles	0.64	0.818 (±0.3178)	3.638 (±6.6927)
	Right iliac	0.90	0.985 (±0.0111)	10.108 (±51.8553)
	Right proximal femur	0.90	0.980 (±0.0195)	13.193 (±68.4094)

The subject device achieved a median *DSC > 0.80*. Furthermore, organs not meeting predefined acceptance criteria were excluded from the product's intended use to ensure reliability and accuracy. In the performance results, it was found that regardless of whether contrast was injected or not, the system achieved the expected performance outcomes.

5.10.Clinical Tests

No clinical test was conducted as part of submission to prove substantial equivalence.

5.11.Conclusion

The subject device has a similar intended use to the predicate device, and the slight difference does not affect the substantial equivalence. In addition, there are no differences in technological characteristics that affect the safety and effectiveness of the subject device relative to the predicate. Moreover, the performance testing results are similar to the predicate device. Therefore, the subject device, QOCA® image Smart RT Contouring System, is substantially equivalent to the predicate device.