GE Medical Systems, LLC
℅ Niki Mavrodieva
Regulatory Affairs Leader
3000 N. Grandview Blvd.
WAUKESHA WI 53188

May 4, 2023

Re: K230082
Trade/Device Name: Auto Segmentation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: April 7, 2023
Received: April 7, 2023

Dear Niki Mavrodieva:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.05.04 13:08:39 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
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)*
K230082

Device Name

Auto Segmentation

Indications for Use *(Describe)*

Auto Segmentation generates a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk which can be used by dosimetrists, medical physicists, and radiation oncologists as initial contours to accelerate workflow for radiation therapy planning. It is the responsibility of the user to verify the processed output contours and user-defined labels for each organ at risk and correct the contours/labels as needed. Auto Segmentation may be used with images acquired on CT scanners, in adult patients.

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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K230082 510(k) SUMMARY

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.92:

Date:	January 06, 2023
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
Primary Contact:	Niki Mavrodieva Regulatory Affairs Leader GE Healthcare Phone: +1 (902) 302-3913 Email: nikolina.mavrodieva@ge.com
Secondary Contacts:	Camille Vidal Senior Director Regulatory Affairs GE Healthcare Phone: +1 (240) 280-5356 Email: camille.vidal@ge.com
Subject Device Name:	Auto Segmentation
Device Classification	Class II
Regulation Number:	21 CFR 892.2050 Medical image management and processing system
Product Code:	QKB

Predicate Device Information

Device Name:	AccuContour
Manufacturer:	Xiamen Manteia Technology LTD.
510(k) Number:	K191928
Regulation Number:	21 CFR 892.2050 Medical image management and processing system
Product Code:	QKB

Reference Devices Information

Device Name:	AdvantageSim MD With CT Atlas-Based Contouring and Re-Planning Options
Manufacturer:	GE Hungary KFT
510(k) Number:	K132045
Regulation Number:	21 CFR 892.5840 Radiation therapy simulation system
Product Code:	KPQ

Device Description

Auto Segmentation is a post-processing software designed to automatically generate contours of organ(s) at risk (OARs) from Computed Tomography (CT) images in the form of a DICOM Radiotherapy Structure Set (RTSS) series. The application is intended as a workflow tool for initial segmentation of OARs to streamline the process of organ at risk delineation. The output of the Auto Segmentation is intended to be used by radiotherapy (RT) practitioners after review and editing, if necessary, and confirming the accuracy of the contours for use in radiation therapy planning.

Auto Segmentation uses deep learning algorithms to generate organ at risk contours for the head and neck, thorax, abdomen and pelvis regions from CT images across 40 organ(s) or organ subregion(s). The automatically generated organ at risk contours are networked to predefined DICOM destination(s), such as review workstations supporting RTSS format, for review and editing, as needed.

The organ at risk contours generated with the Auto Segmentation application are designed to improve the contouring workflow by automatically creating contours for review by the intended users. The application is compatible with CT DICOM images with single energy acquisition modes and may be used with both GE and non-GE CT scanner acquired images (contrast and non-contrast), in adult patients.

Intended Use

Auto Segmentation is intended to be used as a workflow tool for initial anatomy segmentation of organs at risk on CT images as an aid in radiation therapy planning after user confirmation.

Indications for Use

Auto Segmentation generates a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk which can be used by dosimetrists, medical physicists, and radiation oncologists as initial contours to accelerate workflow for radiation therapy planning. It is the responsibility of the user to verify the processed output contours and user-defined labels for each organ at risk and correct the contours/labels as needed. Auto Segmentation may be used with images acquired on CT scanners, in adult patients.

Technology:

The proposed device, Auto Segmentation, employs similar fundamental scientific technology as its predicate device.

Comparisons

The Auto Segmentation software is substantially equivalent to the predicate device, AccuContour (K191928). The proposed device is based on the same fundamental technology as the predicate device using deep learning algorithms for organ at risk segmentation. The proposed device is intended for automatic segmentation only, while the predicate has manual contouring, registration, and other general capabilities. The table below summarizes the substantive feature/technological similarities and differences between the predicate device and the proposed device:

Specification	**Predicate Device** AccuContour (K191928)	**Proposed Device** Auto Segmentation
Indications for Use	It is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.	Auto Segmentation generates a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk which can be used by dosimetrists, medical physicists, and radiation oncologists as initial contours to accelerate workflow for radiation therapy planning. It is the responsibility of the user to verify the processed output contours and user-defined labels for each organ at risk and correct the contours/labels as needed. Auto Segmentation may be used with images acquired on CT scanners, in adult patients.
Contra-indications	None	Same
Patient Population	Adults only	Same
Algorithm	Deep Learning	Same
Compatible Modality	Non-contrast CT images	CT (contrast and non-contrast) images
OAR Segmentation Anatomic Regions	Head & Neck Thorax Abdomen Pelvis	Same
Workflow	Automated	Same
User Interface	Basic result preview of automatic segmentation results. Manual segmentation is possible. Configuration menu.	Automated execution of the software with no user interaction, other than configuration settings. Generated contours are automatically transmitted to review workstation(s) supporting RTSS objects for review and editing, as needed.
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required	Same
Deployment Platform	Cloud and server-based deployment	Server-based deployment

Determination of Substantial Equivalence

Summary of Non-Clinical Testing

Auto Segmentation has successfully completed the design control testing per GE Healthcare's quality system. It was designed under the Quality System Regulations of 21CFR 820 and ISO 13485. No new questions of safety and effectiveness and no unexpected test results were observed.

The following quality assurance measures have been applied to the development of the system:

- Requirement Definition
- Risk Analysis and Control
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Safety Testing (Verification)
- Performance Testing (Verification, Validation)
- Software Release

Auto Segmentation has been successfully verified. The testing and results did not raise any new issues of safety and effectiveness. Software documentation provided is for a "Major" Level of Concern.

The Auto Segmentation algorithms were developed and trained using a dataset of 911 different CT exams from several clinical sites from multiple countries. The original development and training data was used for radiotherapy planning, and so is representative of typical clinical practice for the subject device.

Performance testing to evaluate the device's performance in segmenting organs-at-risk was performed using a database of 302 retrospective CT radiation therapy planning exams, from multiple clinical sites in North America, Asia, and Europe, that is representative of the clinical scenarios where Auto Segmentation is intended to be used. This bench testing dataset was segregated, completely independent and not used in any stage of algorithm development, including training.

The data was acquired using a variety of CT scanners and scanner protocols from different manufacturers. The demographic distribution of the dataset consists of:

- Gender: 87 Female, 160 Male, 55 Unknown
- Age: Adult (18 – 89 years old)
- Ethnicity: Dataset was collected from 9 global sources, including USA, EU, and Asia.

Note: due to anonymization, gender, age, and ethnicity information is not available for all exams.

Ground truth annotations were established following RTOG and DAHANCA clinical guidelines manually by three independent, qualified radiotherapy practitioners. The annotation process was designed to reflect segmentation practices following international clinical guidelines.

The evaluation used the DICE similarity coefficient (DSC) as a primary metric to compare 2552 Auto Segmentation generated contours to ground truth contours, and evaluate performance against pre-defined acceptance DICE values on a per organ basis. These 2552 contours were generated from the 302 unique patient exams in the bench testing dataset.

The acceptance criteria were defined individually for each organ as the target quantitative performance requirement that the segmentation model must reach in order to establish the performance for that specific organ. Acceptance criteria were established from:

- Published performance metrics from deep-learning based or atlas-based FDA cleared products;
- Estimation of expected performance based on organ specific characteristics and clinical justification, where a DICE value for deep-learning or atlas-based FDA cleared devices was not accessible.

The Auto Segmentation device performance results are shown in **Table 1**. The following is a summary of the overall performance evaluation:

Table 1: Summary of Auto Segmentation performance

OAR	**Auto Segmentation** (subject device)		**Acceptance Criteria**	
	Dice Mean	**Lower CI95**	**Type**	**Dice Mean**
Adrenal Left	78.68%	76.63%	Estimated	68.0%
Adrenal Right	72.48%	69.78%	Estimated	68.0%
Bladder	81.50%	78.33%	Deep learning	80.0%
Body	99.50%	99.38%	Atlas-based	98.1%
Brainstem	87.69%	87.15%	Deep learning	88.4%
Chiasma	43.81%	41.03%	Atlas-based	11.7%
Esophagus	81.69%	80.38%	Atlas-based	45.8%
Eye Left	91.32%	89.77%	Deep learning	90.1%
Eye Right	90.25%	88.23%	Deep learning	89.9%
Femur Left	97.65%	97.18%	Atlas-based	71.6%
Femur Right	97.92%	97.78%	Atlas-based	70.8%
Kidney Left	92.53%	90.30%	Deep learning	86.8%
Kidney Right	94.82%	93.48%	Deep learning	85.6%
Lacrimal Gland Left	59.79%	57.65%	Deep learning	50.0%
Lacrimal Gland Right	58.09%	55.81%	Deep learning	50.0%
Lens Left	76.86%	74.80%	Deep learning	73.3%
Lens Right	79.09%	77.40%	Deep learning	75.6%
Liver	94.28%	92.27%	Deep learning	91.1%
Lung Left	97.70%	97.38%	Deep learning	97.4%
Lung Right	97.99%	97.81%	Deep learning	97.8%
Mandible	92.70%	92.36%	Deep learning	94.0%

OAR	Auto Segmentation (subject device)		Acceptance Criteria	
	Dice Mean	**Lower CI95**	**Type**	**Dice Mean**
Optic Nerve Left	79.22%	77.99%	Deep learning	71.1%
Optic Nerve Right	80.20%	78.94%	Deep learning	71.2%
Oral Cavity	87.43%	86.20%	Deep learning	91.0%
Pancreas	80.34%	78.50%	Estimated	73.0%
Parotid Left	84.35%	83.27%	Deep learning	65.0%
Parotid Right	85.55%	84.48%	Deep learning	65.0%
Proximal Bronchial Tree (PBtree)	84.94%	83.71%	Atlas-based	54.8%
Inferior PCM (Pharyngeal Constrictor Muscle)	70.51%	68.72%	Estimated	68.0%
Middle PCM	67.09%	65.21%	Estimated	68.0%
Superior PCM	59.57%	57.85%	Estimated	50.0%
Pericardium	93.58%	92.00%	Atlas-based	84.4%
Pituitary	75.62%	74.12%	Deep learning	78.0%
Prostate	79.67%	77.60%	Atlas-based	52.1%
Spinal Cord	88.55%	87.43%	Deep learning	87.0%
Submandibular Left	86.85%	85.95%	Deep learning	77.0%
Submandibular Right	85.70%	84.79%	Deep learning	78.0%
Thyroid	85.37%	84.27%	Deep learning	83.0%
Trachea	91.02%	90.47%	Atlas-based	69.2%
Whole Brain	98.53%	98.46%	Estimated	93.0%

Note: in "Type" column above, Deep learning means similar device using deep learning technology, while Atlas-based means similar devices using Atlas-based technology. Estimated means acceptance criteria were estimated based on organ specific characteristics and clinical justification.

The subject device performance was superior for all organs with atlas-based predicates. The evaluation of the Dice mean for the Auto Segmentation algorithms demonstrates that the algorithm performance is in line with the performance of the predicate, as well as state of the art, recently cleared similar automated contouring devices.

A subgroup analysis found that the algorithms' performance is consistent across multiple CT system vendors, pixel spacing, slice distance, gender, and geographical subgroups. Known limitations are described in the user documentation.

The results of the algorithm testing demonstrate that Auto Segmentation performs as expected.

Summary of Clinical Testing

A qualitative preference study evaluation comparing to a Likert scale was conducted using a database of sample clinical CT images to demonstrate that the contours generated by the Auto Segmentation application are adequate for radiotherapy planning use. Each contour used in the evaluation was generated using the Auto Segmentation application, and reviewed by three qualified radiotherapy practitioners, who provided an assessment of the adequacy of the subject device generated contours. The evaluators completed their assessments independently and were blinded to the results of the other evaluators' assessments. The results of the algorithm clinical testing shows that the Auto Segmentation generated organ contours are adequate for use in radiotherapy planning.

Substantial Equivalence Conclusion

Auto Segmentation and the predicate have substantially equivalent indications for use, and represent equivalent technological characteristics, including the use of deep learning algorithms.

Auto Segmentation was developed under GE Healthcare's quality system. Design verification and validation, along with bench testing and the clinical reader study provided in this submission demonstrate that the Auto Segmentation software is substantially equivalent and, hence, as safe and effective as the legally marketed predicate device. GE Healthcare's quality system design, verification, and risk management processes did not identify any unexpected results or new questions of safety and effectiveness.

GE Healthcare believes that Auto Segmentation is substantially equivalent to the predicate device and, hence, is safe and effective for its intended use.