



April 1, 2025

GE Healthcare
Allena Holzworth
Regulatory Affairs Leader
500 W. Monroe Street
Chicago, Illinois 60661

Re: K242925

Trade/Device Name: MR Contour DL
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: February 27, 2025
Received: February 27, 2025

Dear Allena Holzworth:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

A handwritten signature in black ink that reads "Lora D. Weidner". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible in the background behind the signature.

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K242925

Device Name

MR Contour DL

Indications for Use (Describe)

MR Contour DL generates a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk which can be used by trained medical professionals. It is intended to aid in radiation therapy planning by generating 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. MR Contour DL is intended to be used with images acquired on MR 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.

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GE HealthCare510(k) Premarket Notification Submission – MR Contour DL

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: February 19, 2025

Submitter: GE HealthCare
500 W. Monroe Street
Chicago, IL 60661

Primary Contact: Allena Holzworth
Regulatory Affairs Leader
GE HealthCare
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Subject Device Name: MR Contour DL

Device Classification Class II

Regulation Number: 21 CFR 892.2050 Medical image management and processing system

Product Code: QKB

Predicate Device Information

Device Name: Auto Segmentation

Manufacturer: GE Medical Systems, LLC

510(k) Number: K230082

Regulation Number: 21 CFR 892.2050 Medical image management and processing system

Product Code: QKB

Reference Device 1 Information

Device Name: AutoContour Model RADAC V2

Manufacturer: Radformation, Inc.

510(k) Number: K220598

Regulation Number: 21 CFR 892.2050 Medical image management and processing system

Produce Code: QKB

Reference Device 2 Information

Device Name:	Contour ProtégéAI
Manufacturer:	MIM Software Inc.
510(k) Number:	K213976
Regulation Number:	21 CFR 892.2050 Medical image management and processing system
Product Code:	QKB

Device Description

MR Contour DL is a post processing application intended to assist a clinician by generating contours of organ at risk (OAR) from MR images in the form of a DICOM Radiotherapy Structure Set (RTSS) series. MR Contour DL is designed to automatically contour the organs in the head/neck, and in the pelvis for Radiation Therapy (RT) planning of adult cases. The output of the MR Contour DL 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.

MR Contour DL uses customizable input parameters that define RTSS description, RTSS labeling, organ naming and coloring. MR Contour DL does not have a user interface of its own and can be integrated with other software and hardware platforms. MR Contour DL has the capability to transfer the input and output series to the customer desired DICOM destination(s) for review.

MR Contour DL uses deep learning segmentation algorithms that have been designed and trained specifically for the task of generating organ at risk contours from MR images. MR Contour DL is designed to contour 37 different organs or structures using the deep learning algorithms in the application processing workflow.

The input of the application is MR DICOM images in adult patients acquired from compatible MR scanners. In the user-configured profile, the user has the flexibility to choose both the covered anatomy of input scan and the specific organs for segmentation. The proposed device has been tested on GE HealthCare MR data.

Intended Use

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

Indications for Use

MR Contour DL generates a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk which can be used by trained medical professionals. It is intended to aid in radiation therapy planning by generating 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. MR Contour DL is intended to be used with images acquired on MR scanners, in adult patients.

Technology:

The proposed device, MR Contour DL, employs similar fundamental scientific technology as its predicate device. Both the proposed device and the predicate device use deep learning algorithms to segment organs at risk.

Comparisons

MR Contour DL software is substantially equivalent to the predicate device, Auto Segmentation (K230082). The proposed device is based on the same fundamental technology as the predicate device using deep learning algorithms for organ at risk segmentation. The comparisons of the intended use, indications for use, and devices technical characteristics demonstrate that the proposed device, MR Contour DL, is as safe and effective and substantially equivalent to that of the predicate device. MR Contour DL did not introduce any new questions of safety and effectiveness.

The tables below summarize the substantive feature/technological similarities and differences between the proposed device, predicate device and reference devices.

Table 1: Comparison of Intended Use between Proposed Device and Predicate Device

Items	Proposed MR Contour DL	Predicate: Auto Segmentation (K230082)	Comparison
Intended Use	MR Contour DL is intended to be used as a workflow tool for initial anatomy segmentation of organs at risk on MR images as an aid in radiation therapy planning after user confirmation.	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.	Both the proposed device and the predicate device are intended to be used as a workflow tool for initial anatomy segmentation of organs at risk as an aid in radiation therapy planning after user confirmation. The proposed device is intended for post-processing MR images, whereas the predicate is intended for post-processing of CT images. All features and performance of the proposed device have been verified and validated per GE HealthCare’s quality system. No safety and effectiveness issues were raised. In addition, the performance testing conducted on MR Contour DL successfully demonstrate the devices performance, particularly the anatomy segmentation of organs at risk on MR images. The intended use of the proposed device falls within the general intended use of the predicate device and do not create a new Intended Use.

Table 2: Comparison of Indications for Use between Proposed Device and Predicate Device

Items	Proposed MR Contour DL	Predicate: Auto Segmentation (K230082)	Comparison
Indications for Use	MR Contour DL generates a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk which can be used by trained medical professionals. It is intended to aid in radiation therapy	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	Substantially Equivalent – Both the proposed device and the predicate device are indicated to generate a Radiotherapy Structure Set (RTSS) DICOM with segmented organs at risk. Both the proposed device and the predicate device are: <ul style="list-style-type: none"> Used by trained medical

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Items	Proposed MR Contour DL	Predicate: Auto Segmentation (K230082)	Comparison
	<p>planning by generating 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. MR Contour DL is intended to be used with images acquired on MR scanners, in adult patients.</p>	<p>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.</p>	<p>professionals, including the professions listed by the predicate device.</p> <ul style="list-style-type: none"> • Intended to aid in radiation therapy planning by generating initial contours to accelerate workflow for radiation therapy planning. • Declare that it is the responsibility of the user to verify the processed output contours and user-defined labels for each organ at risk and to correct the contours/labels as needed. <p>MR Contour DL is intended to be used with images acquired on MR scanners in adult patients while the predicate device is intended to be used on images acquired on CT scanners in adult patients.</p> <p>All features and performance of the proposed device have been verified and validated per GEHC’s quality system. No safety and effectiveness issues were raised. Additionally, the testing performed on MR Contour DL demonstrates the devices performance, particularly the anatomy segmentation of organs at risk on MR images. The indications for use for the proposed device is substantially equivalent to that of the predicate.</p>

Table 3: Comparison of technical characteristics between proposed device, predicate device, and reference devices

Items	Proposed MR Contour DL	Predicate: Auto Segmentation (K230082)	Reference 1: AutoContour Model RADAC V2 (K220598)	Reference 2: Contour ProtégéAI (K213976)	Comparison
Product Code	QKB	QKB	QKB	QKB	Identical
Patient Population	Adult only	Adult only	Adult only	Adult only	Identical

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Items	Proposed MR Contour DL	Predicate: Auto Segmentation (K230082)	Reference 1: AutoContour Model RADAC V2 (K220598)	Reference 2: Contour ProtégéAI (K213976)	Comparison
Intended Users	Radiologists, Radiation oncologists, Dosimetrists, and Medical Physicists	Radiation Oncologists, Dosimetrists, and Medical Physicists	Medical Professionals who do radiation therapy treatment planning	Trained Medical Professionals	Substantially Equivalent – both the proposed device and the predicate device are intended for trained medical professionals in the radiation oncology field
Algorithm	Deep Learning	Deep Learning	Machine Learning/Deep Learning	Machine Learning	Substantially Equivalent – both the proposed device and the predicate device contain deep learning auto segmentation algorithms
Compatible Modality	MR images	CT images	CT images and MR images	CT images and MR images	Substantially Equivalent – While the predicate device is only intended to segment CT Images, both reference devices are intended to segment both CT and MR images. Reference 1 uses DICOM-compliant image data (CT or MR) to automatically contour various structures of interest for RT planning. Reference device 2 is intended to assist in the automated processing of digital medical images of modalities CT and MR to create contours using machine learning algorithms. The proposed device aligns with the performance of commercially available products on the market, specifically Reference Devices 1 and 2.
OAR Segmentation on Anatomic Regions	Head/neck Pelvis	Head/neck Thorax Abdomen Pelvis	Head/neck Thorax Abdomen pelvis	Head/neck Prostate Thorax Abdomen Lungs and Liver	Substantially Equivalent – Both the predicate and proposed device cover the Head/neck and Pelvis regions.
Workflow	Automated	Automated	Manual and Automated	Automated	Identical
User Interface	Automated execution of the software with no user interaction, other than configuration settings. Generated	Automated execution of the software with no user interaction, other than configuration settings. Generated	Contains both an automated processing component, Data Visualization, and Graphical User Interface	Designed for use in the processing of medical images and operates on Windows, Mac, and Linux	Identical

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Items	Proposed MR Contour DL	Predicate: Auto Segmentation (K230082)	Reference 1: AutoContour Model RADAC V2 (K220598)	Reference 2: Contour ProtégéAI (K213976)	Comparison
	contours are automatically transmitted to review workstation(s) supporting RTSS objects for review and editing, as needed.	contours are automatically transmitted to review workstation(s) supporting RTSS objects for review and editing, as needed.		computer systems. Deployed on a remote server using the MIMcloud service for data management and transfer; or locally on the workstation or server running MIM software.	
Compatible Scanner Models	Compatible on MR Scanners, DICOM compliance required.	No limitation on scanner model, DICOM compliance required.	No limitation on scanner model, DICOM compliance required	No limitation on scanner model, DICOM compliance required	<p>Substantially Equivalent – The proposed device is compatible with MR scanner models and DICOM compliance is required. The proposed device has only been tested on GEHC data. If a non-GEHC MR image is sent to MR Contour DL, a notice message will display after contouring.</p> <p>The predicate device has no limitation on scanner models and DICOM compliance is also required. This difference does not raise any new safety or effectiveness concerns.</p>
Deployment Platform	Server-based deployment	Server-based deployment	Cloud and server-based deployment	Cloud-based deployment and locally deployed (or installed)	Identical – Both the proposed device and the predicate device are deployed on Edison HealthLink (EHL), GE Healthcare’s computational platform providing hosting infrastructure and services.

Determination of Substantial EquivalenceSummary of Non-Clinical Testing

MR Contour DL 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

MR Contour DL has been successfully verified. The testing and results did not raise any new concerns of safety and effectiveness. Software documentation provided is for **Enhanced Documentation**.

The bench testing assessed the performance of MR Contour DL using the DICE score as a primary metric by comparing the segmentation accuracy of the proposed device to that of the predicate and reference devices for supported organs at risk. The MR Contour DL algorithm's capability was validated using a database of 105 retrospectively collected exams with a total of 1350 MR Contour DL generated contours for head/neck and 510 MR Contour DL generated contours for pelvis that were compared to ground truth contours generated by qualified radiotherapy practitioners. The result of the algorithm bench testing showed that MR Contour DL performs as expected.

The test data included (23 head/neck, 32 pelvis) cases from data cohorts which were collected independently from the development data and cases (27 head/neck, 23 pelvis) which were separated from the development data cohorts before the models were trained. Therefore in total test data included 50 head/neck and 55 pelvis cases.

Table 4 demonstrates the performance metrics (DSC, HD95) measured with ground-truth (see column ground-truth). The acceptance criterion was defined with DSC for each individual organ, based on the size of the organ (small 50%, medium 65%, large 80%). The HD95 metric was compared to the predicate device by evaluating the Lower Bound (LBCI95) and Upper Bound (UBCI95) of the 95% Confidence Interval against the mean HD95 of the predicate device for each organ. MR Contour DL's performance was considered improved from the predicate if UBCI95 was less than the HD95 mean of the predicate device, and performance was considered equivalent to the predicate if the HD95 mean of the predicate device was between LBCI95 and UBCI95. In summary, MR Contour DL had an improved or equivalent HD95 value in 24/28 of the organs analyzed and an average HD95 performance of 4.7 mm, which is smaller than the average corresponding HD95 values of the predicate device (for the Hausdorff Distance metric a smaller HD95 value signifies better segmentation). Therefore, the performance of the proposed device is substantially equivalent to that of the cleared predicate device.

The evaluation for ground-truth involved 50 head/neck cases (of 50 subjects). The test data was collected from USA (72%) and European (NL, 28%) clinical sites, acquired with GEHC (76%) and other MR scanners, using standard 2-dimensional T2 (FRFSE, TSE) imaging protocol. The test data was collected from male (64%) and female subjects (36%), with average age 58.9 years (SD 14.2) and weight 78.2kg (SD 16.3). The test data included healthy subjects (42%) and patients (58%) with different types of Squamous Cell Carcinoma (Oropharynx, Hypopharynx, Larynx, Salivary gland).

The evaluation with ground-truth involved 55 pelvis cases of (55 subjects). The test data was collected from USA (58%) and UK (42%) clinical sites, acquired with GEHC (100%) MR scanners, using standard 3-dimensional T2 CUBE imaging protocol. The test data was collected from male (81%) and female (19%) subjects, with average age 64.4 years (SD 13.1) and weight 82.3kg (SD 20.0). The test data included healthy subject (31%) and patients (69%) with different types of pelvis cancer (prostate, rectal, anal).

Ground-truth was created following: 1) manual contour was delineated by GEHC operators trained using international guidelines (DAHANCA, RTOG), 2) manual contours were revised (corrected and approved) by three (2 USA, 1 EUR) board certified radiation oncologists, 3) all (3) independently validated ground-truth contours were incorporated in the performance evaluation. The test set and the ground-truth were stored separately from the development data.

The performance was evaluated on the whole test set, as well as on the following 6 sub-cohorts: 1) region (USA, Europe), 2) subject (patient, healthy), and 3) gender (male, female). The mean DSC accuracy (incorporating all 37 organs) was 81.1% for all, 81.3% for male, 83.4% for female, 82.7% for USA, 80.4% for Europe, 81.6% for patient, and 80.5% for healthy cases, which demonstrate the overall model performance was similar in all sub-cohorts.

Summary of Clinical Testing

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

Table 4 demonstrates the performance metric (Likert score) measured in the clinical testing (see column Reader-study). The predefined acceptance criterion was the mean Likert Score for each organ shall be greater than or equal to 3.0, with the following interpretation of the Likert Score: 1 – unacceptable (recontouring is needed), 2 – poor (significant correction is needed), 3 – good (some correction is needed), 4 – very good (minor correction is needed), 5 – excellent (no correction is needed).

The clinical testing was performed on a subset of the data used for non-clinical (bench) testing. The 30 head/neck and 40 pelvis cases were randomly selected from the original set of 50 head/neck and 55 pelvis cases by ensuring that all clinical sites, scan types, and subject cohorts are represented in the test set.

The clinical testing was performed as follows: 1) The auto-contour was generated with MR Contour DL for the selected test cases, 2) the auto-contours were reviewed and scored by three (2 USA, 1 Europe) certified radiation oncologists and, 3) all (3) independently provided Likert Scores were incorporated in the performance evaluation.

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Table 4: Performance metrics for all organs (L – left, R – right, G – glottic, SG – supraglottic, PCM- Pharyngeal Constrictor Muscle, DSC – DICE Similarity Coefficient, HD95 – 95th percentile Hausdorff Distance).

Organ	Anatomy region	Ground-truth					Reader-study	
		Number of cases	DSC Acceptance criteria	DSC MEAN	HD95 MEAN	HD95 value compared to predicate device	Number of cases	Likert score MEAN
bladder	pelvis	53	80%	92.4%	4.7	Improved	40	3.7
bowel-bag	pelvis	40	80%	90.3%	13.3	N/A	40	3.3
brainstem	head/neck	50	65%	94.3%	2.1	Improved	30	4.0
chiasm	head/neck	50	50%	72.7%	2.5	Improved	30	3.5
eye-L	head/neck	50	65%	95.5%	1.4	Improved	30	4.3
eye-R	head/neck	50	65%	95.4%	1.4	Improved	30	4.3
femoral-head-L	pelvis	53	80%	93.7%	4.5	Not-Improved	40	4.2
femoral-head-R	pelvis	51	80%	93.5%	5.3	Not-Improved	40	4.1
head-body	head/neck	50	80%	99.3%	1.6	Improved	30	3.8
inner-ear-L	head/neck	50	50%	88.4%	1.4	N/A	30	4.5
inner-ear-R	head/neck	50	50%	88.3%	1.3	N/A	30	4.4
lacrimal-L	head/neck	50	50%	67.4%	4.2	Equivalent	30	4.0
lacrimal-R	head/neck	50	50%	65.6%	4.4	Equivalent	30	4.0
larynx-G	head/neck	49	50%	67.1%	3.9	N/A	30	3.5
larynx-SG	head/neck	50	65%	85.3%	4.9	N/A	30	3.8
lens-L	head/neck	50	50%	86.7%	1.2	Improved	30	4.4
lens-R	head/neck	50	50%	86.1%	1.3	Improved	30	4.5
mandible	head/neck	50	65%	89.8%	2.8	Equivalent	30	3.6
optic-nerve-L	head/neck	50	50%	73.4%	2.9	Equivalent	30	3.7
optic-nerve-R	head/neck	50	50%	72.3%	2.6	Improved	30	3.7
oral-cavity	head/neck	50	65%	92.5%	3.7	Improved	30	3.7
parotid-L	head/neck	50	65%	85.9%	4.9	Improved	30	3.8
parotid-R	head/neck	50	65%	84.6%	6.0	Improved	30	3.7
PCM-inf	head/neck	44	50%	53.6%	7.0	Not-Improved	30	3.5
PCM-mid	head/neck	50	50%	60.1%	6.1	Equivalent	30	3.8
PCM-sup	head/neck	50	50%	57.6%	6.8	Improved	30	3.4
pelvis-body	pelvis	50	80%	97.5%	10.0	Not-Improved	40	4.1
penile-bulb	pelvis	39	50%	67.5%	7.3	N/A	30	3.3
pituitary	head/neck	50	50%	73.7%	2.5	Equivalent	30	3.6
prostate	pelvis	43	65%	83.0%	5.6	Equivalent	30	3.0
rectum	pelvis	53	65%	79.6%	19.8	N/A	40	3.6
seminal-vesicles	pelvis	43	65%	69.2%	7.3	N/A	30	3.3
spinal-cord	head/neck	50	65%	90.3%	2.2	Improved	30	4.1
submandibular-L	head/neck	49	65%	86.4%	3.4	Equivalent	30	3.9
submandibular-R	head/neck	49	65%	85.4%	3.3	Equivalent	30	3.9
urethra	pelvis	43	50%	35.8%	9.5	N/A	30	3.4
whole-brain	head/neck	50	80%	98.8%	1.8	Improved	30	3.7

GE HealthCare**510(k) Premarket Notification Submission – MR Contour DL**

Substantial Equivalence Conclusion

MR Contour DL and the predicate device have substantially equivalent indications for use, and represent equivalent technological characteristics, including the use of deep learning algorithms.

MR Contour DL 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 MR Contour DL 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 MR Contour DL is substantially equivalent to the predicate device and, hence, is safe and effective for its intended use.