Limbus AI Inc.
Jonathan Giambattista
Director - Software
2431 Glamis Place
Regina, SK S4N3K9
Canada

October 9, 2024

Re: K241837
Trade/Device Name: Limbus Contour
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: July 15, 2024
Received: July 15, 2024

Dear Jonathan Giambattista:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241837

Device Name

Limbus Contour

Indications for Use *(Describe)*

Limbus Contour is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal contours for input to radiation treatment planning.

Supported image modalities are Computed Tomography and Magnetic Resonance. The Limbus Contour Software assists in the following scenarios:
Operates in conjunction with radiation treatment planning systems or DICOM viewing systems to load, save, and display medical images and contours for treatment evaluation and treatment planning.
Creation, transformation, and modification of contours for applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy and archiving contours for patient follow-up.
Localization and definition of healthy anatomical structures.

Limbus Contour is not intended for use with digital mammography.

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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K241837

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

Limbus AI Inc.
2431 Glamis Pl
Regina, Saskatchewan, Canada, S4V1A5
Tel: 1-306-502-5982

Contact Person: Jon Giambattista
Date Prepared: October 9, 2024

II. DEVICE

Name of Device:	Limbus Contour
Classification Name:	Radiological Image Processing System
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Product Classification Code:	QKB

III. PREDICATE DEVICE

Predicate Manufacturer:	Limbus AI, Inc.
Predicate Trade Name:	Limbus Contour
Predicate 510(k):	K230575

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Limbus Contour is a stand-alone software medical device. It is a single purposes cross-platform application for automatic contouring (segmentation) of CT/MRI DICOM images via pre-trained and expert curated machine learning models. The software is intended to be used by trained medical professionals to derive contours for input to radiation treatment planning. The Limbus Contour software segments normal tissues using machine learning models and further post-processing on machine learning model prediction outputs. Limbus Contour does not display or store DICOM images and relies on existing radiotherapy treatment planning systems (TPS) and DICOM image viewers for display and modification of generated segmentations. Limbus Contour interfaces with the user's operating system file system (importing DICOM image .dcm files and exporting segmented DICOM RT-Structure Set .dcm files).

V. INDICATIONS FOR USE

Limbus Contour is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal contours for input to radiation treatment planning.
Supported image modalities are Computed Tomography and Magnetic Resonance. The Limbus Contour Software assists in the following scenarios:

- Operates in conjunction with radiation treatment planning systems to load, save, and display medical images and contours for treatment evaluation and treatment planning.
- Creation, transformation, and modification of contours for applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy and archiving contours for patient follow-up.

- Localization and definition of anatomical structures.

Limbus Contour is not intended for use with digital mammography.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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 are identical with the exception that the predicate has support for MacOS while the subject device does not and the predicate has less structures for automatic contouring available.
- Materials – The predicate and subject device are software-only devices and do not inherently contain material.
- Design – The predicate and subject device have equivalent designs.
- Energy Source – The predicate and subject device are software-only devices, powered by the computer system.
- Performance Testing – The predicate and subject device were both validated using an automatic contouring test to ensure the contours were accurate.

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
Classification Regulation	892.2050 – Medical image management and processing system	892.2050 – Medical image management and processing system	Same
Product Code	QKB	LLZ	Similar; Both product codes refer to the same CFR 892.2050 - Medical image management and processing system
Indications for Use	Limbus Contour is a software only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. The Limbus Contour Software assists in the following scenarios: • Operates in conjunction with radiation treatment planning systems or DICOM viewing systems to load, save, and display medical images and contours for treatment evaluation and treatment planning. • Creation, transformation, and modification of contours for	Limbus Contour is a software only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. The Limbus Contour Software assists in the following scenarios: • Operates in conjunction with radiation treatment planning systems or DICOM viewing systems to load, save, and display medical images and contours for treatment evaluation and treatment planning. • Creation, transformation, and modification of contours for	Same

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
	applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy and archiving contours for patient follow-up. • Localization and definition of healthy anatomical Structures. Limbus Contour is not intended for use with digital mammography.	applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy and archiving contours for patient follow-up. • Localization and definition of healthy anatomical Structures. Limbus Contour is not intended for use with digital mammography.	
Intended User	Healthcare providers	Healthcare providers	Same
Machine Learning Algorithm	Locked algorithm; Deep Learning model	Locked algorithm; Deep Learning model	Same
Contouring Modes	Automatic	Automatic	Same
Supported Image Modalities	CT; MR	CT; MR	Same
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM compliance required.	Same
Compatible Treatment Planning System	No Limitation on TPS model	No Limitation on TPS model	Same
Result Visualization	Limbus Contour has no data visualization. Data processing is automated and does not require user interaction. A control interface is provided for system administration and configuration only. Visualization software must be used to facilitate the review and edit of the generated contours.	Limbus Contour has no data visualization. Data processing is automated and does not require user interaction. A control interface is provided for system administration and configuration only. Visualization software must be used to facilitate the review and edit of the generated contours.	Same
Structures Available for Contouring	CT Structures ● A_Aorta ● A_Aorta_I ● A_Celiac ● A_LAD ● A_Mesenteric_S ● A_Pulmonary ● Bag_Bowel ● Bag_Bowel_Extend ● Bag_Bowel_Full ● Bag_Bowel_S ● Bladder ● Body ● Bone_Hyoid	CT Structures ● A_Aorta ● A_Aorta_Base ● A_Aorta_I ● A_Celiac ● A_LAD ● A_Mesenteric_S ● A_Pulmonary ● Atrium_L ● Atrium_R ● Bowel_Bag ● Bowel_Bag_Extend ● Bowel_Bag_Full ● Bowel_Bag_Superior	Similar; The subject device adds new structures for existing supported image modalities (CT/MR)

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
	• Bone_Ilium_L • Bone_Ilium_R • Bone_Ilium • Bone_Mandible • Bowel • Bowel_Extend • Bowel_Full • Bowel_S • BrachialPlex_L • BrachialPlex_R • BrachialPlexs • Brain • Brainstem • Breast_L • Breast_R • Breasts • Bronchus • Canal_Anal • CaudaEquina • Cavity_Oral • Chestwall_L • Chestwall_R • Chestwalls • Clavicle_L • Clavicle_R • Cochlea_L • Cochlea_R • Colon_Sigmoid • Cornea_L • Cornea_R • Duodenum • Esophagus • Eye_L • Eye_R • Eyes • Femur_Head_L • Femur_Head_R • Femur_Heads • Gallbladder • Glnd_Lacrimal_L • Glnd_Lacrimal_R • Glnd_Submand_L • Glnd_Submand_R • Glnd_Thyroid • GreatVes • Heart • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • Kidney_L • Kidney_R • Kidneys • Larynx • Lens_L • Lens_R • Lips • Liver • LN_Ax_Sclav_L	• Bowel • Bowel_Extend • Bowel_Full • Bowel_Superior • Bladder • Body • Body+Mask • Bone_Hyoid • Bone_Ilium_L • Bone_Ilium_R • Bone_Ilium • Bone_Ischium_L • Bone_Ischium_R • Bone_Mandible • Bone_Pelvic • BoneMarrow_Pelvic • BrachialPlex_L • BrachialPlex_R • BrachialPlexs • Brain • Brainstem • Breast_Implant_L • Breast_Implant_R • Breast_L • Breast_R • Breasts • Bronchus • Canal_Anal • Carina • CaudaEquina • Cavity_Oral • Cerebellum • Chestwall_L • Chestwall_R • Chestwall • Clavicle_L • Clavicle_R • Cochlea_L • Cochlea_R • Colon_Sigmoid • Cornea_L • Cornea_R • Duodenum • Esophagus • Eye_L • Eye_R • Eyes • Femur_Head_L • Femur_Head_R • Femur_Heads • Gallbladder • Glnd_Lacrimal_L • Glnd_Lacrimal_R • Glnd_Submand_L • Glnd_Submand_R • Glnd_Thyroid • GreatVes • Heart • Heart+A_Pulm	

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
	• LN_Ax_Sclav_R • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_L • LN_Ax_L2_R • LN_Ax_L3_L • LN_Ax_L3_R • LN_Sclav_L • LN_Sclav_R • LN_IMN_L • LN_IMN_R • LN_Neck_L • LN_Neck_R • LN_Neck_234_L • LN_Neck_234_R • LN_Neck_2347AB_L • LN_Neck_2347AB_R • LN_Neck_IA • LN_Neck_IA6 • LN_Neck_IB_L • LN_Neck_IB_R • LN_Neck_II_L • LN_Neck_II_R • LN_Neck_III_L • LN_Neck_III_R • LN_Neck_IV_L • LN_Neck_IV_R • LN_Neck_V_L • LN_Neck_V_R • LN_Neck_VI • LN_Neck_VIIAB_L • LN_Neck_VIIAB_R • LN_Pelvis • Lung_L • Lung_R • Lungs • Musc_Constrict • Musc_PecMinor_L • Musc_PecMinor_R • Musc_Sclmast_L • Musc_Sclmast_R • OpticChiasm • OpticNrv_L • OpticNrv_R • Pancreas • Parotid_L • Parotid_R • PelvisVessels • PenileBulb • Pituitary • Prostate • Prostate+SeminalVes • PubicSymphys • Rectum • Retina_L • Retina_R • Ribs_L • Ribs_R • Ribs	• Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • InternalAuditoryCanal_L • InternalAuditoryCanal_R • Kidney_L • Kidney_R • Kidneys • Larynx • Lens_L • Lens_R • Lips • Liver • Lung_L • Lung_R • Lungs • Mesorectum • Musc_Constrict • Musc_PecMinor_L • Musc_PecMinor_R • Musc_Sclmast_L • Musc_Sclmast_R • Optics • OpticChiasm • OpticNrv_L • OpticNrv_R • Pancreas • Parotid_L • Parotid_R • PelvisVessels • PenileBulb • Pericardium • Pericardium+A_Pulm • Pituitary • Prostate • Prostate+SeminalVes • ProstateBed • PubicSymphys • Rectum • Retina_L • Retina_R • Ribs_L • Ribs_R • Ribs • Sacrum • SeminalVes • Skin • SpinalCanal • SpinalCord • Spleen • Sternum • Stomach • Trachea • Uterus+Cervix • V_Venacava_I • V_Venacava_S • Vagina • VB_C1	

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
	• Sacrum • SeminalVes • Skin • SpinalCanal • SpinalCord • Spleen • Sternum • Stomach • Trachea • Uterus_Cervix • V_Venacava_I • V_Venacava_S • Vagina • Ventricle_L MR Structures • Brainstem • Cornea_L • Cornea_R • Eye_L • Eye_R • Hippocampus_L • Hippocampus_R • Optics • PenileBulb • Prostate • Retina_L • Retina_R • SeminalVes	• VB_C2 • VB_C3 • VB_C4 • VB_C5 • VB_C6 • VB_C7 • VB_L1 • VB_L2 • VB_L3 • VB_L4 • VB_L5 • VB_T01 • VB_T02 • VB_T03 • VB_T04 • VB_T05 • VB_T06 • VB_T07 • VB_T08 • VB_T09 • VB_T10 • VB_T11 • VB_T12 • VBs • Ventricle_L • Ventricle_R • Bladder_HDR • Bowel_HDR • Canal_Anal_HDR • Colon_Sigmoid_HDR • Rectum_HDR • Urethra_HDR • Bladder_CBCT • Femur_Head_L_CBCT • Femur_Head_R_CBCT • LN_Pelvics_CBCT • Prostate_CBCT • Rectum_CBCT • SeminalVes_CBCT MR Structures • Bladder • Brainstem • Cornea_L • Cornea_R • Eye_L • Eye_R • Femur_Head_L • Femur_Head_R • Hippocampus_L • Hippocampus_R • Optics • PenileBulb • PubicSymphys • Prostate • Rectum • Retina_L • Retina_R • Sacrum	

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
		• SeminalVes • Bladder_HDR • Bowel_HDR • Canal_Anal_HDR • Colon_Sigmoid_HDR • Rectum_HDR • Urethra_HDR	
Training Characteristics and datasets	The architecture for the neural network models used in our device borrows its primary structure from the U-Net (Ronneberger 2015) and ResUNet (Diakogiannisa 2020). We use the Adam optimization algorithm (Kingma 2014) and the Sørensen–Dice coefficient loss function (Sørensen 1948) to train the network. The models are trained with examples of medical images and the corresponding human-generated contours for the region of interest. During training, an image is shown to the model, and the model generates a contour. The contour generated by the model is compared to the ground truth human-generated contour. The error between the generated and ground truth contours is used to adjust the parameters (weights) of the model. Backpropagation is the algorithm that uses the error to adjust the model parameters. The scans used in training and validating the models were collected from a variety of anonymized and pseudo-anonymized datasets that included human-generated contours. Datasets are from publicly available clinical trials, and from the company's clinical and research partners. Anatomical segmentation accuracy investigation by Wong 2020 demonstrated that Limbus Contour outputs are highly comparable to expert contours (for the evaluated Head and Neck and Prostate treatment sites). Specifically, for	architecture for the neural network models used in our device borrows its primary structure from the U-Net (Ronneberger 2015) and ResUNet (Diakogiannisa 2020). We use the Adam optimization algorithm (Kingma 2014) and the Sørensen–Dice coefficient loss function (Sørensen 1948) to train the network. The models are trained with examples of medical images and the corresponding human-generated contours for the region of interest. During training, an image is shown to the model, and the model generates a contour. The contour generated by the model is compared to the ground truth human-generated contour. The error between the generated and ground truth contours is used to adjust the parameters (weights) of the model. Backpropagation is the algorithm that uses the error to adjust the model parameters. The scans used in training and validating the models were collected from a variety of anonymized and pseudo-anonymized datasets that included human-generated contours. Datasets are from publicly available clinical trials, and from the company's clinical and research partners. Anatomical segmentation accuracy investigation by Wong 2020 demonstrated that Limbus Contour outputs are highly comparable to expert contours (for the evaluated Head and Neck and Prostate treatment sites). Specifically, for most	Same

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
	most of the anatomical structures examined, the Dice Scores (DSC) between Limbus Contour and expert contours were not significantly different from the inter-observer expert variability baselines. The investigation by Wong, Huang, Wells et al., 2021 evaluated implementation of Limbus Contour prospectively at two Canadian institutions. Limbus Contour was used to generate OAR and CTVs for all patients undergoing RT for a central nervous system (CNS), head and neck (H&N), or prostate cancer. Automatic contours were generated on approximately 551 eligible cases. 203 surveys were collected on 27 CNS, 54 H&N, and 93 prostate RT plans, resulting in an overall survey compliance rate of 32%. The majority of OAR automatic contours required minimal edits subjectively (mean editing score ≤ 2) and objectively (mean DSC and 95% HD was ≥ 0.90 and ≤ 2.0 mm, respectively). Overall, thousands of total structures were analyzed across all investigations covering all supported anatomical sites to provide a substantial sample of device outputs to draw conclusions that anatomical structure contour outputs offer good geometric alignment with expert contours, require minimal editing, and significantly reduce the time needed for contouring.	of the anatomical structures examined, the Dice Scores (DSC) between Limbus Contour and expert contours were not significantly different from the inter-observer expert variability baselines. The investigation by Wong, Huang, Wells et al., 2021 evaluated implementation of Limbus Contour prospectively at two Canadian institutions. Limbus Contour was used to generate OAR and CTVs for all patients undergoing RT for a central nervous system (CNS), head and neck (H&N), or prostate cancer. Automatic contours were generated on approximately 551 eligible cases. 203 surveys were collected on 27 CNS, 54 H&N, and 93 prostate RT plans, resulting in an overall survey compliance rate of 32%. The majority of OAR automatic contours required minimal edits subjectively (mean editing score ≤ 2) and objectively (mean DSC and 95% HD was ≥ 0.90 and ≤ 2.0 mm, respectively). Overall, thousands of total structures were analyzed across all investigations covering all supported anatomical sites to provide a substantial sample of device outputs to draw conclusions that anatomical structure contour outputs offer good geometric alignment with expert contours, require minimal editing, and significantly reduce the time needed for contouring.	
Computer Platform & Operating System	Operating System • Windows 10 / Windows Server 2016 and Above Hardware Requirements • 2 GHz or faster multicore processor • 8 GB of RAM • For GPU versions, a CUDA capable NVIDIA GPU is required	Operating System • Windows 10 / Windows Server 2016 and Above Hardware Requirements • 2 GHz or faster multicore processor • 16 GB of RAM • For GPU versions, a CUDA capable NVIDIA GPU is required	Similar; Limbus Contour v1.8.0 requires 16 GB of RAM instead of 8 GB to support added structures for automatic contouring

Item	Limbus Contour v1.8	Limbus Contour v1.7 - K230575	Similarities / Differences
Cloud-based deployment	No	No	Same
Locally deployed (or installed)	Yes	Yes	Same
Data Transfer	Exported Limbus Contour DICOM RT-Structure Set files are imported into the Treatment Planning System or DICOM Viewer through interactions with the File System	Exported Limbus Contour DICOM RT-Structure Set files are imported into the Treatment Planning System or DICOM Viewer through interactions with the File System	Same

Training and Validation Datasets

The scans used in training and validating the models were collected from a variety of anonymized and pseudo-anonymized datasets that included human-generated contours as ground truths.

Datasets are from publicly available clinical trials, and from the company's clinical and research partners. All data is acquired, licensed, stored, and managed in accordance with the company's dataset management procedure.

The fundamental criteria for including a dataset for training and validation is that the scans were generated for use in the course of radiotherapy treatment. Training dataset ground truth contours were reviewed and edited when necessary by our in-house clinicians and radiation oncologist to ensure consistency with established standards and guidelines for contouring.

To reduce bias in the training data, the following selection criteria are in place:

- Datasets from multiple clinical sites (institutions) are included
- Datasets include clinical sites of multiple country origin. Including but not limited to:
    - United States
    - Canada
    - United Kingdom
    - France
    - Germany
    - Italy
    - Netherlands
    - Switzerland
    - Australia
    - New Zealand
    - Singapore
- Ground truth annotations are consistent with recognized consensus contouring guidelines (RTOG, RTOG 1106, RTOG 0848, EMBRACE II, DAHANCA, NRG, ESTRO, ACROP, EPTN)
- Datasets include different makes and models of imaging devices (CT/MR scans)

    - Sampling data from many different institutions and countries ensures a variety of imaging devices are captured
    - Imaging devices included in training datasets include the following manufacturers: GE, Siemens, Phillips, Toshiba, Elekta
    - All imaging data was captured as part of standard clinic protocols for image acquisition in the course of radiation treatment planning. All imaging data is DICOM format and conforms to the DICOM standard (version 3.0 and newer)
- The scans and ground truth contours in the datasets are from the general population of patients receiving radiotherapy treatment. The datasets are not restricted on the basis of age, ethnicity, race, gender, or disease states. A mix of healthy patients and patients with disease were used as training data.
    - By sampling a large volume of data from a variety of institutions, countries, and including publically available datasets; a general population of patients receiving radiotherapy treatment is created. Multiple scan locations were used in the training data. For example, the scans used to train the parotid gland model were head and neck scans, while the scans used to train the bladder model were pelvic scans. The scans come from many different makes and models of imaging devices for both the CT and MRI scans.
    - The total number of unique scans included in training datasets exceeds 10,000 scans.

The following table shows the number of patients used in the training and validation data for each model. For each model, the training and validation sets are kept completely separate from the testing sets.

Models underwent additional final performance testing on a separate set of scans (see VII. PERFORMANCE DATA). Validation scans are used only to determine at what epoch to stop model training.

Structure	Modality	Body site	Number of training scans	Number of validation scans
Canal_Anal	CT	Pelvis	1084	50
Canal_Anal (Female)	CT	Pelvis	383	43
Canal_Anal_HDR	CT	Pelvis	466	49
Canal_Anal_HDR	MRI	Pelvis	304	34
A_Aorta	CT	Thorax	715	50
A_Aorta_Base	CT	Thorax	331	37
A_Aorta_I	CT	Abdomen	352	40
Applicator_Cylinder (beta)	CT	Pelvis	217	24
Applicator_Ring (beta)	CT	Pelvis	163	19
Bladder	CT	Pelvis	1105	50
Bladder_CBCT	CT	Pelvis	356	39
Bladder (Female)	CT	Pelvis	378	43
Bladder_HDR	CT	Pelvis	712	49
Bladder_HDR	MRI	Pelvis	303	34

Bowel	CT	Pelvis	697	50
Bowel_Extend	CT	Pelvis	697	50
Bowel_Extend (Female)	CT	Pelvis	697	50
Bowel (Female)	CT	Pelvis	697	50
Bowel_Full	CT	Pelvis	697	50
Bowel_Full (Female)	CT	Pelvis	697	50
Bowel_HDR	CT	Pelvis	682	50
Bowel_HDR	MRI	Pelvis	305	36
Bowel_Superior	CT	Abdomen	453	50
Bladder	MRI	Pelvis	579	50
Bowel_Bag	CT	Pelvis	697	50
Bowel_Bag_Extend	CT	Pelvis	697	50
Bowel_Bag_Extend (Female)	CT	Pelvis	697	50
Bowel_Bag (Female)	CT	Pelvis	697	50
Bowel_Bag_Full	CT	Pelvis	697	50
Bowel_Bag_Full (Female)	CT	Pelvis	697	50
Bowel_Bag_Superior	CT	Abdomen	453	50
Brain	CT	Head Neck	452	47
Brainstem	CT	Head Neck	614	50
Brainstem	MRI	Head Neck	241	27
Breasts	CT	Thorax	660	50
Breast_L	CT	Thorax	660	50
Wire_Breast_L (beta)	CT	Thorax	660	50
Breast_R	CT	Thorax	660	50
Wire_Breast_R (beta)	CT	Thorax	660	50
LN_Ax_Sclav_L	CT	Thorax	343	39
LN_Ax_Sclav_R	CT	Thorax	343	39
LN_Ax_L1_L	CT	Thorax	343	39
LN_Ax_L1_R	CT	Thorax	343	39
LN_Ax_L2_L	CT	Thorax	343	39
LN_Ax_L2_R	CT	Thorax	343	39
LN_Ax_L3_L	CT	Thorax	343	39
LN_Ax_L3_R	CT	Thorax	343	39
LN_Sclav_L	CT	Thorax	343	39
LN_Sclav_R	CT	Thorax	343	39
A_Celiac	CT	Thorax	435	44
Carina	CT	Thorax	865	50
CaudaEquina	CT	Pelvis	663	50
Cerebellum	CT	Head Neck	135	16

Chestwall	CT	Thorax	223	25
Chestwall_L	CT	Thorax	223	25
CW2cm_L	CT	Thorax	223	25
Chestwall_R	CT	Thorax	223	25
CW2cm_R	CT	Thorax	223	25
OpticChiasm	CT	Head Neck	1254	140
Clavicle_L	CT	Head Neck	104	12
Clavicle_R	CT	Head Neck	104	12
Cochlea_L	CT	Head Neck	248	29
Cochlea_R	CT	Head Neck	248	29
Musc_Constrict	CT	Head Neck	186	21
Cornea_L	CT	Head Neck	729	50
Cornea_L	MRI	Head Neck	199	23
Cornea_R	CT	Head Neck	729	50
Cornea_R	MRI	Head Neck	199	23
Bone_Ilium	CT	Pelvis	214	24
Bone_Ilium_L	CT	Pelvis	214	24
Bone_Ilium_R	CT	Pelvis	214	24
LN_Neck_L	CT	Head Neck	374	42
LN_Neck_R	CT	Head Neck	374	42
LN_Neck_IA	CT	Head Neck	112	13
LN_Neck_IA6	CT	Head Neck	112	13
LN_Neck_VI	CT	Head Neck	112	13
LN_Neck_234_L	CT	Head Neck	672	50
LN_Neck_234_R	CT	Head Neck	672	50
LN_Neck_2347AB_L	CT	Head Neck	672	50
LN_Neck_2347AB_R	CT	Head Neck	672	50
LN_Neck_IB_L	CT	Head Neck	672	50
LN_Neck_IB_R	CT	Head Neck	672	50
LN_Neck_II_L	CT	Head Neck	672	50
LN_Neck_II_R	CT	Head Neck	672	50
LN_Neck_III_L	CT	Head Neck	672	50
LN_Neck_III_R	CT	Head Neck	672	50
LN_Neck_IV_L	CT	Head Neck	672	50
LN_Neck_IV_R	CT	Head Neck	672	50
LN_Neck_V_L	CT	Head Neck	672	50
LN_Neck_V_R	CT	Head Neck	672	50
LN_Neck_VIIA_L	CT	Head Neck	672	50
LN_Neck_VIIA_R	CT	Head Neck	672	50
LN_Neck_VIIAB_L	CT	Head Neck	672	50

LN_Neck_VIIAB_R	CT	Head Neck	672	50
LN_Neck_VIIB_L	CT	Head Neck	672	50
LN_Neck_VIIB_R	CT	Head Neck	672	50
Mesorectum	CT	Pelvis	302	33
Duodenum	CT	Abdomen	382	37
Esophagus	CT	Thorax	1643	50
ESTRO_LN_IMN_L	CT	Thorax	409	45
ESTRO_LN_IMN_R	CT	Thorax	409	45
ESTRO_LN_IMN_L_Expand	CT	Thorax	409	45
ESTRO_LN_IMN_R_Expand	CT	Thorax	409	45
ESTRO_LN_Ax_IP_L	CT	Thorax	395	44
ESTRO_LN_Ax_IP_R	CT	Thorax	395	44
ESTRO_LN_Ax_L1_L	CT	Thorax	395	44
ESTRO_LN_Ax_L1_R	CT	Thorax	395	44
ESTRO_LN_Ax_L2+IP_Fill_L	CT	Thorax	395	44
ESTRO_LN_Ax_L2+IP_Fill_R	CT	Thorax	395	44
ESTRO_LN_Ax_L2_L	CT	Thorax	404	45
ESTRO_LN_Ax_L2_R	CT	Thorax	404	45
ESTRO_LN_Ax_L3_L	CT	Thorax	404	45
ESTRO_LN_Ax_L3_R	CT	Thorax	404	45
ESTRO_LN_Sclav_L	CT	Thorax	409	45
ESTRO_LN_Sclav_R	CT	Thorax	409	45
Eyes	CT	Head Neck	729	50
Femur_Heads	CT	Pelvis	511	50
Femur_Head_L	CT	Pelvis	511	50
Femur_Head_L_CBCT	CT	Pelvis	139	17
Femur_Head_L	MRI	Pelvis	67	8
Femur_Head_R	CT	Pelvis	511	50
Femur_Head_R_CBCT	CT	Pelvis	139	17
Femur_Head_R	MRI	Pelvis	67	8
Gallbladder	CT	Abdomen	539	50
Eye_L	CT	Head Neck	729	50
Eye_L	MRI	Head Neck	199	23
Eye_R	CT	Head Neck	729	50
Eye_R	MRI	Head Neck	199	23
GreatVes	CT	Thorax	715	50
Heart	CT	Thorax	1000	50
Heart+A_Pulm	CT	Thorax	33	4

Pericardium+A_Pulm	CT	Thorax	33	4
Hippocampus_L	CT	Head Neck	104	12
Hippocampus_L	MRI	Head Neck	144	17
Hippocampus_R	CT	Head Neck	104	12
Hippocampus_R	MRI	Head Neck	144	17
Humerus_L	CT	Thorax	114	13
Humerus_R	CT	Thorax	114	13
InternalAuditoryCanal_L	CT	Head Neck	253	27
InternalAuditoryCanal_R	CT	Head Neck	253	27
LN_IMN_L	CT	Thorax	574	50
LN_IMN_R	CT	Thorax	574	50
LN_IMN_L_Expand	CT	Thorax	574	50
LN_IMN_R_Expand	CT	Thorax	574	50
Breast_Implant_L	CT	Thorax	75	9
Breast_Implant_R	CT	Thorax	75	9
LN_Inguinal_L	CT	Pelvis	282	32
LN_Inguinal_R	CT	Pelvis	282	32
Bone_Ischium_L	CT	Pelvis	234	25
Bone_Ischium_R	CT	Pelvis	234	25
V_Venacava_I	CT	Thorax	1000	50
Kidneys	CT	Abdomen	1018	50
Kidney_L	CT	Abdomen	1018	50
Kidney_R	CT	Abdomen	999	50
Atrium_L	CT	Thorax	331	37
A_LAD	CT	Thorax	588	50
Glnd_Lacrimal_L	CT	Head Neck	281	32
Glnd_Lacrimal_R	CT	Head Neck	281	32
Larynx	CT	Head Neck	365	30
Lens_L	CT	Head Neck	670	50
Lens_R	CT	Head Neck	670	50
Liver	CT	Abdomen	1000	50
Lips	CT	Head Neck	265	30
Bone_Hyoid	CT	Head Neck	326	35
Musc_PecMinor_L	CT	Thorax	398	42
Musc_PecMinor_R	CT	Thorax	398	42
Sternum	CT	Thorax	261	30
PubicSymphys	CT	Pelvis	540	50
PubicSymphys	MRI	Pelvis	617	49
Lungs	CT	Thorax	572	50
Lung_L	CT	Thorax	572	50

Lung_R	CT	Thorax	567	50
Ventricle_L	CT	Thorax	331	37
Bone_Mandible	CT	Head Neck	521	50
OpticNrv_L	CT	Head Neck	1254	140
OpticNrv_R	CT	Head Neck	1254	140
Optics	CT	Head Neck	1254	140
Optics	MRI	Head Neck	214	24
Cavity_Oral	CT	Head Neck	243	27
Pancreas	CT	Abdomen	765	50
Parotid_L	CT	Head Neck	688	50
Parotid_R	CT	Head Neck	688	50
Bone_Pelvic	CT	Pelvis	35	4
LN_Pelvics	CT	Pelvis	921	50
LN_Pelvics_CBCT	CT	Pelvis	189	24
BoneMarrow_Pelvic	CT	Pelvis	35	4
PelvisVessels	CT	Pelvis	921	50
PenileBulb	CT	Pelvis	657	50
PenileBulb	MRI	Pelvis	293	34
Pericardium	CT	Thorax	225	24
Pituitary	CT	Head Neck	295	33
BrachialPlexs	CT	Thorax	774	50
BrachialPlex_L	CT	Thorax	774	50
BrachialPlex_R	CT	Thorax	774	50
Prostate	CT	Pelvis	888	50
Prostate_CBCT	CT	Pelvis	267	29
ProstateBed	CT	Pelvis	150	16
ProstateFiducials (beta)	CT	Pelvis	888	50
Prostate	MRI	Pelvis	1698	50
Prostate+SeminalVes	CT	Pelvis	902	50
Bronchus	CT	Thorax	865	50
A_Pulmonary	CT	Thorax	670	75
Atrium_R	CT	Thorax	331	37
Rectum	CT	Pelvis	1084	50
Rectum_CBCT	CT	Pelvis	369	42
Rectum (Female)	CT	Pelvis	215	24
Rectum_HDR	CT	Pelvis	334	35
Rectum_HDR	MRI	Pelvis	304	34
Rectum	MRI	Pelvis	571	50
Retina_L	CT	Head Neck	729	50
Retina_L	MRI	Head Neck	199	23

Retina_R	CT	Head Neck	729	50
Retina_R	MRI	Head Neck	199	23
Ribs	CT	Thorax	84	11
Ribs_L	CT	Thorax	84	11
Ribs_R	CT	Thorax	84	11
Ventricle_R	CT	Thorax	331	37
Sacrum	CT	Pelvis	195	22
Sacrum	MRI	Pelvis	333	35
Musc_Sclmast_L	CT	Head Neck	86	10
Musc_Sclmast_R	CT	Head Neck	86	10
Colon_Sigmoid	CT	Pelvis	497	50
Colon_Sigmoid (Female)	CT	Pelvis	497	50
Colon_Sigmoid_HDR	CT	Pelvis	494	48
Colon_Sigmoid_HDR	MRI	Pelvis	240	24
A_Mesenteric_S	CT	Thorax	428	43
Glnd_Submand_L	CT	Head Neck	573	50
Glnd_Submand_R	CT	Head Neck	573	50
Spleen	CT	Abdomen	137	16
SeminalVes	CT	Pelvis	902	50
SeminalVes_CBCT	CT	Pelvis	235	26
SeminalVes	MRI	Pelvis	589	50
V_Venacava_S	CT	Thorax	384	43
SpaceOARVue (beta)	CT	Pelvis	36	5
SpinalCord	CT	Head Neck/Thorax	1000	49
SpinalCanal	CT	Head Neck/Thorax	1000	49
Stomach	CT	Abdomen	1414	50
Lobe_Temporal_L	CT	Head Neck	211	23
Lobe_Temporal_R	CT	Head Neck	211	23
Glnd_Thyroid	CT	Thorax	685	50
Trachea	CT	Thorax	865	50
Urethra_HDR	CT	Pelvis	244	25
Urethra_HDR	MRI	Pelvis	236	24
Uterus+Cervix	CT	Pelvis	360	40
Vagina	CT	Pelvis	95	11
VB_C1	CT	Head Neck	132	13
VB_C2	CT	Head Neck	132	13
VB_C3	CT	Head Neck	132	13
VB_C4	CT	Head Neck	132	13
VB_C5	CT	Head Neck	132	13

VB_C6	CT	Head Neck	132	13
VB_C7	CT	Head Neck	132	13
VB_L1	CT	Pelvis	219	24
VB_L2	CT	Pelvis	219	24
VB_L3	CT	Pelvis	219	24
VB_L4	CT	Pelvis	219	24
VB_L5	CT	Pelvis	219	24
VB_T01	CT	Thorax	230	26
VB_T02	CT	Thorax	230	26
VB_T03	CT	Thorax	230	26
VB_T04	CT	Thorax	230	26
VB_T05	CT	Thorax	230	26
VB_T06	CT	Thorax	230	26
VB_T07	CT	Thorax	230	26
VB_T08	CT	Thorax	230	26
VB_T09	CT	Thorax	230	26
VB_T10	CT	Thorax	230	26
VB_T11	CT	Thorax	230	26
VB_T12	CT	Thorax	230	26
VBs	CT	All	260	28

VII. PERFORMANCE DATA

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

Sterilization & Shelf-life Testing

The subject device is a software-only device. Therefore sterilization and shelf-life are not applicable.

Biocompatibility

The subject device is a software-only device. There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device

Electrical safety and electromagnetic compatibility (EMC)

The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type; therefore, this section is not applicable.

Software Verification and Validation Testing

Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". The enhanced level of documentation was provided.

Two different types of verification testing were conducted to verify the software requirements: Manual and Automated. All tests passed, demonstrating that the software performance is in accordance with the stated software requirements.

Validation testing of the following functions of the Limbus Contour application demonstrated that the software meets user needs and intended uses and to support substantial equivalence:

- Automatic Contouring – Validation Test (Benchtop performance testing)

Automatic Contouring - Validation Test

Each structure undergoes performance testing prior to release. The objective of the testing is to verify that the software outputs meet the input requirements and that the software can consistently and accurately fulfill its intended use by contouring images to a level deemed sufficient based on published data, and expert opinion. This is achieved through testing the system functionality with controlled test datasets of medical scans with manual segmentations of structures that have been previously treated clinically and reviewed by a medical expert.

For each structure, a set of at least 10 patient scans is used for testing. A single scan may be used to test multiple structures. These test scans are randomly selected from our total pool of patient scans that contain the structure and are not included in training or validation of the models. Our total pool of patient scans that contain the structures were selected to reflect the general population of patients receiving radiation treatments.

Each of the 10 scans selected randomly for performance testing is run through the Limbus Contour software: this constitutes a single trial. Note that the same scan may appear in the test set of multiple structures, but each scan need only be run through the software once. The output of each trial is a DICOM RT-Structure file generated by the software that may contain multiple structure contours. Structure contours will be generated for scans of the appropriate body site only. For example, for pelvic scans only pelvic structures (like BLADDER) will be generated (not thorax or head and neck structures).

Test inputs:

- A patient test scan on the computer file system
- User interaction to select, import, choose structures, and start-contouring the patient test scans listed above.

Test outputs:

- A DICOM RT-Structure file written to the test computer file system (may contain multiple structure contours)

Supplemental data required:

- Each patient test scan has a corresponding DICOM RT-Structure file which contains ground truth contours for some structures. The ground truth contours are from multiple experts at multiple institutions. They have all been reviewed by a board certified radiation oncologist to ensure structures are labeled properly and contoured according to clinical trial guidelines.

Contours generated by Limbus Contour are compared to ground truth expert contours using the Sørensen–Dice Similarity Coefficient (Dice Similarity Coefficient, or DSC, for short) (Sørensen 1948). DSC is a measurement of the volumetric overlap of two contours. It is widely used in medical imaging, and specifically for evaluating the performance of autosegmentation approaches (Balagopal 2018, Cardenas 2018, Dong 2019, van Harten 2019, Nikolov 2018, Trullo 2017, Liang 2019, Ren 2018, Wong 2019, Wong 2020).

Mean DSC values and standard deviations from published machine learning autosegmention models as references for the pass/fail criteria for benchtop testing. For each structure, we compare the lower edge of the 95% confidence interval to the mean minus the standard deviation of the reference model's DSC. If the lower edge of the confidence interval is less than the reference mean minus the standard deviation, the test fails.

The table below includes the Test DSC threshold from the reference studies. Note that there is a wide range of mean DSC scores across structures: large, easily identifiable structures (e.g. lungs) will have higher DSC scores than small, hard-to-identify structures (e.g. lacrimal glands).

Limbus Mean DSC and DSC Std Dev and DSC lower 95% conf edge are compared with the Test DSC Threshold. Full testing results for all structures are provided in the table below:

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
A_Aorta	0.909095	0.0455771	10	0.87649337	0.81	Passed
A_Aorta_Base	0.979588	0.0286193	10	0.95911641	0.81	Passed
A_Aorta_I	0.938016	0.10304303	10	0.86430858	0.81	Passed
A_Celiac	0.781502	0.27272084	10	0.58642282	0.26	Passed
A_LAD	0.692766	0.06590144	10	0.64562622	0.26	Passed
A_Mesenteric_S	0.857257	0.14185425	10	0.75578763	0.26	Passed
A_Pulmonary	0.901867	0.03499015	10	0.87683829	0.85	Passed
Applicator_Cylinder (beta)	0.80111733	0.33037573	15	0.60816274	0.374	Passed
Applicator_Ring (beta)	0.963863	0.07306595	10	0.9115984	0.374	Passed
Atrium_L	0.977044	0.0180652	10	0.96412183	0.79	Passed
Atrium_R	0.978451	0.01852677	10	0.96519867	0.78	Passed
Bladder	0.96601238	0.05220935	21	0.94024138	0.935	Passed
Bladder	0.963518	0.01177413	10	0.95509588	0.88	Passed
Bladder_CBCT	0.959173	0.04229406	10	0.92891975	0.91	Passed
Bladder_HDR	0.931167	0.06094679	10	0.88757132	0.56674243	Passed
Bladder_HDR	0.896883	0.13171833	10	0.80266393	0.79	Passed
BoneMarrow_Pelvic	0.995414	0.00407252	10	0.9925009	0.805	Passed
Bone_Hyoid	0.85411417	0.04163051	12	0.82693015	0.77	Passed
Bone_Ilium_L	0.9888075	0.01103973	12	0.98159874	0.76	Passed
Bone_Ilium_R	0.99058833	0.00575056	12	0.98683332	0.76	Passed
Bone_Ischium_L	0.938985	0.01573502	10	0.92772963	0.76	Passed
Bone_Ischium_R	0.93923	0.01613541	10	0.92768822	0.76	Passed
Bone_Mandible	0.94024769	0.01266685	13	0.93230094	0.922	Passed
Bone_Pelvic	0.98383	0.00511637	10	0.98017022	0.929	Passed
Bowel	0.90743217	0.06592406	23	0.87633846	0.74	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
Bowel_Bag	0.93979478	0.03659061	23	0.92253647	0.752	Passed
Bowel_Bag_Extend	0.971576	0.01582803	20	0.9635702	0.752	Passed
Bowel_Bag_Full	0.9679985	0.01354157	20	0.9611492	0.752	Passed
Bowel_Bag_Superior	0.93686455	0.09357214	11	0.8730466	0.752	Passed
Bowel_Extend	0.941682	0.03040818	20	0.92630159	0.74	Passed
Bowel_Full	0.92351381	0.03444493	21	0.90651148	0.74	Passed
Bowel_HDR	0.841368	0.05558462	10	0.80160792	0.2008343	Passed
Bowel_HDR	0.55831818	0.24969816	11	0.38801937	0.31	Passed
Bowel_Superior	0.90214273	0.03756911	11	0.87651989	0.74	Passed
BrachialPlex_L	0.691605	0.10786794	10	0.61444628	0.39	Passed
BrachialPlex_R	0.693809	0.11005989	10	0.61508237	0.39	Passed
Brain	0.992205	0.00251205	16	0.99078444	0.988	Passed
Brainstem	0.90334688	0.03859191	16	0.88152315	0.695	Passed
Brainstem	0.925526	0.02877815	10	0.90494078	0.725	Passed
Breast_Implant_L	0.992884	0.00662727	10	0.98814346	0.865	Passed
Breast_Implant_R	0.973663	0.03491225	10	0.94869001	0.865	Passed
Breast_L	0.954514	0.02763163	10	0.9347489	0.726	Passed
Breast_R	0.93952091	0.04383671	11	0.90962345	0.7345	Passed
Bronchus	0.839515	0.06515951	10	0.79290593	0.76	Passed
CW2cm_L	0.998955	0.00118886	10	0.9981046	0.72	Passed
CW2cm_R	0.999376	0.00101477	10	0.99865013	0.72	Passed
Canal_Anal	0.87596095	0.13633659	21	0.808664	0.803	Passed
Canal_Anal_HDR	0.942891	0.04773688	10	0.90874446	0.56167132	Passed
Canal_Anal_HDR	0.610295	0.35031087	10	0.35971511	0.31	Passed
Carina	1	0	10	1	0.77	Passed
CaudaEquina	0.882098	0.06633305	10	0.83464949	0.722	Passed
Cavity_Oral	0.913113	0.0386665	10	0.88545458	0.8	Passed
Cerebellum	0.983219	0.01399611	10	0.97320748	0.83	Passed
Chestwall_L	0.95907091	0.00299448	11	0.95702862	0.72	Passed
Chestwall_R	0.95957182	0.00327572	11	0.95733772	0.72	Passed
Clavicle_L	0.98014375	0.01256694	16	0.97303715	0.93	Passed
Clavicle_R	0.981565	0.01013648	16	0.97583282	0.93	Passed
Cochlea_L	0.702311	0.10183115	10	0.62947045	0.533	Passed
Cochlea_R	0.686758	0.14712802	10	0.58151627	0.545	Passed
Colon_Sigmoid	0.81625381	0.15924956	21	0.73764681	0.704	Passed
Colon_Sigmoid_HDR	0.865505	0.12156688	10	0.77854734	0.30928644	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
Colon_Sigmoid_HDR	0.753036	0.15966944	10	0.6388233	0.47	Passed
Cornea_L	0.96183182	0.06990272	11	0.91415686	0.489	Passed
Cornea_L	0.913718	0.03513108	10	0.88858848	0.489	Passed
Cornea_R	0.96934727	0.05299966	11	0.93320051	0.498	Passed
Cornea_R	0.927223	0.02302511	10	0.91075297	0.498	Passed
Duodenum	0.828433	0.18461132	10	0.69637919	0.649	Passed
ESTRO_LN_Ax_IP_L	0.984552	0.0225043	10	0.96845451	0.79	Passed
ESTRO_LN_Ax_IP_R	0.988801	0.01830441	10	0.97570773	0.796	Passed
ESTRO_LN_Ax_L1_L	0.997122	0.00681545	10	0.99224686	0.66	Passed
ESTRO_LN_Ax_L1_R	0.967503	0.01693458	10	0.95538957	0.66	Passed
ESTRO_LN_Ax_L2+IP_Fill_L	0.992986	0.01314147	10	0.98358582	0.73	Passed
ESTRO_LN_Ax_L2+IP_Fill_R	0.994206	0.01093726	10	0.9863825	0.73	Passed
ESTRO_LN_Ax_L2_L	0.995192	0.01077199	10	0.98748672	0.73	Passed
ESTRO_LN_Ax_L2_R	0.997352	0.00448639	10	0.99414286	0.73	Passed
ESTRO_LN_Ax_L3_L	0.993382	0.00884358	10	0.98705612	0.51	Passed
ESTRO_LN_Ax_L3_R	0.992149	0.01468854	10	0.98164218	0.51	Passed
ESTRO_LN_IMN_L	0.980597	0.02745317	10	0.96095955	0.39	Passed
ESTRO_LN_IMN_L_Expand	0.982079	0.05662552	10	0.94157436	0.39	Passed
ESTRO_LN_IMN_R	0.974402	0.04214952	10	0.94425214	0.39	Passed
ESTRO_LN_IMN_R_Expand	0.977852	0.06968747	10	0.92800405	0.39	Passed
ESTRO_LN_Sclav_L	0.97586	0.03136266	10	0.95342606	0.7	Passed
ESTRO_LN_Sclav_R	0.98735	0.02268151	10	0.97112575	0.7	Passed
Esophagus	0.83741083	0.02651585	12	0.82009643	0.67	Passed
Eye_L	0.93511824	0.03324782	17	0.91687796	0.894	Passed
Eye_L	0.950337	0.01463563	10	0.93986803	0.847	Passed
Eye_R	0.94191706	0.03257919	17	0.92404361	0.902	Passed
Eye_R	0.939666	0.03581356	10	0.9140483	0.849	Passed
Femur_Head_L	0.961299	0.00888921	10	0.95494049	0.93	Passed
Femur_Head_L	0.938162	0.04781144	10	0.90396214	0.77	Passed
Femur_Head_L_CBCT	0.977939	0.01378171	10	0.96808085	0.88	Passed
Femur_Head_R	0.961381	0.01105991	10	0.95346976	0.937	Passed
Femur_Head_R	0.948586	0.02852155	10	0.92818433	0.77	Passed
Femur_Head_R_CBCT	0.989667	0.01081208	10	0.98193304	0.88	Passed
Gallbladder	0.946422	0.05882969	10	0.9043407	0.809	Passed
Glnd_Lacrimal_L	0.76574538	0.0785035	13	0.71649497	0.489	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
Glnd_Lacrimal_R	0.73474077	0.09508335	13	0.67508872	0.498	Passed
Glnd_Submand_L	0.838183	0.08845188	10	0.77491273	0.725	Passed
Glnd_Submand_R	0.882672	0.0245712	10	0.86509605	0.595	Passed
Glnd_Thyroid	0.840575	0.03434333	10	0.81600897	0.716	Passed
GreatVes	0.956281	0.01660489	10	0.9444034	0.81	Passed
Heart	0.95488833	0.02805647	12	0.93656793	0.89	Passed
Heart+A_Pulm	0.995663	0.01079707	10	0.98793977	0.89	Passed
Hippocampus_L	0.897474	0.14363431	10	0.79473135	0.45	Passed
Hippocampus_L	0.801092	0.07687695	10	0.74610136	0.618	Passed
Hippocampus_R	0.841933	0.23470004	10	0.67405037	0.45	Passed
Hippocampus_R	0.804229	0.07348396	10	0.75166539	0.618	Passed
Humerus_L	0.981592	0.03366976	10	0.95750778	0.93	Passed
Humerus_R	0.983804	0.02794829	10	0.96381239	0.93	Passed
InternalAuditoryCanal_L	0.719663	0.27119782	10	0.52567325	0.41	Passed
InternalAuditoryCanal_R	0.778302	0.29907667	10	0.5643703	0.41	Passed
Kidney_L	0.97211	0.0055787	10	0.96811951	0.83	Passed
Kidney_R	0.971235	0.00508737	10	0.96759597	0.85	Passed
LN_Ax_L1_L	0.93347	0.03827463	10	0.90609188	0.66	Passed
LN_Ax_L1_R	0.957366	0.01855924	10	0.94409044	0.66	Passed
LN_Ax_L2_L	0.797847	0.03448156	10	0.77318209	0.73	Passed
LN_Ax_L2_R	0.836689	0.03793359	10	0.80955483	0.73	Passed
LN_Ax_L3_L	0.841469	0.02407574	10	0.82424745	0.51	Passed
LN_Ax_L3_R	0.833202	0.05413932	10	0.79447576	0.51	Passed
LN_Ax_Sclav_L	0.854859	0.07708553	10	0.79971917	0.66	Passed
LN_Ax_Sclav_R	0.839354	0.0636715	10	0.79380932	0.66	Passed
LN_IMN_L	0.681072	0.05716488	10	0.64018155	0.39	Passed
LN_IMN_L_Expand	0.974158	0.08171958	10	0.9157034	0.39	Passed
LN_IMN_R	0.754624	0.0588019	10	0.71256258	0.39	Passed
LN_IMN_R_Expand	0.969235	0.09728747	10	0.89964457	0.39	Passed
LN_Inguinal_L	0.987752	0.01196273	10	0.97919497	0.779	Passed
LN_Inguinal_R	0.975856	0.01828094	10	0.96277951	0.779	Passed
LN_Neck_IA	0.88038818	0.10469436	11	0.80898467	0.41	Passed
LN_Neck_IA6	0.94597364	0.03537206	11	0.92184923	0.896	Passed
LN_Neck_IB_L	0.918553	0.02691603	10	0.89929977	0.896	Passed
LN_Neck_IB_R	0.916248	0.01954066	10	0.90227042	0.896	Passed
LN_Neck_III_L	0.924377	0.02716647	10	0.90494463	0.752	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
LN_Neck_III_R	0.903805	0.03651978	10	0.87768214	0.775	Passed
LN_Neck_II_L	0.921425	0.02096226	10	0.90643054	0.894	Passed
LN_Neck_II_R	0.919918	0.02031001	10	0.9053901	0.894	Passed
LN_Neck_IV_L	0.837067	0.10669372	10	0.76074821	0.655	Passed
LN_Neck_IV_R	0.813474	0.07643769	10	0.75879757	0.655	Passed
LN_Neck_L	0.86875	0.04264226	12	0.84090532	0.779	Passed
LN_Neck_R	0.86855	0.04499896	12	0.83916643	0.779	Passed
LN_Neck_VI	0.93822083	0.07273804	12	0.89072412	0.722	Passed
LN_Neck_VIIAB_L	0.704562	0.14161814	10	0.60326153	0.55	Passed
LN_Neck_VIIAB_R	0.684087	0.15673354	10	0.57197437	0.55	Passed
LN_Neck_VIIA_L	0.973697	0.03639132	10	0.94766603	0.54	Passed
LN_Neck_VIIA_R	0.963045	0.0518865	10	0.92593022	0.54	Passed
LN_Neck_VIIB_L	0.979443	0.02540021	10	0.96127405	0.69	Passed
LN_Neck_VIIB_R	0.9727	0.02326651	10	0.9560573	0.71	Passed
LN_Neck_V_L	0.899668	0.05719485	10	0.85875611	0.785	Passed
LN_Neck_V_R	0.855186	0.05671539	10	0.81461707	0.775	Passed
LN_Pelvics	0.90169318	0.05091482	22	0.877139	0.779	Passed
LN_Pelvics_CBCT	0.974742	0.04202674	10	0.94467997	0.58	Passed
LN_Sclav_L	0.96093	0.05712461	10	0.92006835	0.7	Passed
LN_Sclav_R	0.958498	0.02948648	10	0.93740611	0.7	Passed
Larynx	0.898777	0.05827018	10	0.85709592	0.77	Passed
Lens_L	0.78292471	0.08119035	17	0.73838241	0.616	Passed
Lens_R	0.76047471	0.07902615	17	0.71711973	0.449	Passed
Lips	0.824696	0.14948194	10	0.71777049	0.68	Passed
Liver	0.97773385	0.01147248	13	0.9705364	0.92	Passed
Lobe_Temporal_L	0.944744	0.07569022	10	0.89060224	0.83	Passed
Lobe_Temporal_R	0.948456	0.06837365	10	0.89954784	0.83	Passed
Lung_L	0.983115	0.00654768	10	0.9784314	0.96	Passed
Lung_R	0.983649	0.00652109	10	0.97898441	0.96	Passed
Mesorectum	0.827965	0.05209883	10	0.79069833	0.779	Passed
Musc_Constrict	0.869097	0.05737849	10	0.82805376	0.61	Passed
Musc_PecMinor_L	0.869259	0.04744788	10	0.83531919	0.79	Passed
Musc_PecMinor_R	0.863584	0.06177418	10	0.81939649	0.796	Passed
Musc_Sclmast_L	0.946117	0.02773018	10	0.9262814	0.803	Passed
Musc_Sclmast_R	0.945291	0.03302699	10	0.92166656	0.803	Passed
OpticChiasm	0.65929882	0.1679447	17	0.56716174	0.41	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
OpticNrv_L	0.82576941	0.06203798	17	0.79173441	0.73	Passed
OpticNrv_R	0.82894294	0.06130553	17	0.79530977	0.72	Passed
Optics	0.764846	0.05410538	10	0.72614403	0.504	Passed
Pancreas	0.884343	0.09900704	10	0.81352255	0.769	Passed
Parotid_L	0.88352083	0.06794505	12	0.83915386	0.778	Passed
Parotid_R	0.88281667	0.05035732	12	0.84993419	0.803	Passed
PelvisVessels	0.914998	0.02637213	10	0.89613382	0.26	Passed
PenileBulb	0.84850818	0.04605243	11	0.81709956	0.705	Passed
PenileBulb	0.73231	0.27283179	10	0.53715145	0.46	Passed
Pericardium	0.984828	0.0185493	10	0.97155955	0.8688	Passed
Pericardium+A_Pulm	0.994973	0.01235765	10	0.98613348	0.89	Passed
Pituitary	0.75041867	0.15158537	15	0.66188586	0.41	Passed
Prostate	0.934093	0.02193268	10	0.91840439	0.88	Passed
Prostate	0.915164	0.03096645	10	0.89301348	0.8	Passed
ProstateBed	0.74691333	0.1454049	15	0.6619902	0.5	Passed
ProstateFiducials (beta)	0.61422	0.24931989	10	0.43587968	0.41	Passed
Prostate_CBCT	0.961269	0.04241179	10	0.93093154	0.79	Passed
PubicSymphys	0.943743	0.02100908	10	0.92871505	0.76	Passed
PubicSymphys	0.779585	0.11210947	10	0.69939229	0.54	Passed
Rectum	0.88681762	0.08654191	21	0.84409976	0.803	Passed
Rectum	0.934619	0.02030278	10	0.92009628	0.77	Passed
Rectum_CBCT	0.963103	0.02896341	10	0.94238526	0.87	Passed
Rectum_HDR	0.918553	0.09535355	10	0.85034592	0.56167132	Passed
Rectum_HDR	0.781	0.15188698	10	0.67235415	0.58	Passed
Retina_L	0.90761364	0.1929304	11	0.7760315	0.489	Passed
Retina_L	0.953271	0.04079533	10	0.92408981	0.489	Passed
Retina_R	0.91191636	0.1905022	11	0.78199031	0.498	Passed
Retina_R	0.92854	0.05520214	10	0.88905351	0.498	Passed
Ribs_L	0.94473545	0.00563264	11	0.94089389	0.81	Passed
Ribs_R	0.94621636	0.00495204	11	0.94283898	0.81	Passed
Sacrum	0.97012438	0.01642714	16	0.96083483	0.82	Passed
Sacrum	0.966632	0.04786265	10	0.9323955	0.77	Passed
SeminalVes	0.82148	0.16089309	10	0.70639202	0.5	Passed
SeminalVes	0.833995	0.05384245	10	0.79548111	0.39	Passed
SeminalVes_CBCT	0.904653	0.05295257	10	0.86677565	0.621	Passed
SpaceOARVue (beta)	0.866934	0.0421535	10	0.8367813	0.5	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
SpinalCanal	0.8971765	0.06232767	20	0.86565125	0.722	Passed
SpinalCord	0.87788679	0.06353613	28	0.8507265	0.722	Passed
Spleen	0.98238429	0.00724712	14	0.97800307	0.958	Passed
Sternum	0.968506	0.00927831	10	0.96186916	0.8	Passed
Stomach	0.92353818	0.04262548	11	0.89446681	0.64	Passed
Trachea	0.900195	0.04891354	10	0.86520679	0.77	Passed
Urethra_HDR	0.68898	0.26984128	10	0.49596059	0.26	Passed
Urethra_HDR	0.558433	0.30664371	10	0.33908855	0.26	Passed
Uterus+Cervix	0.923876	0.07561527	10	0.86978785	0.8525	Passed
VB_C1	0.871119	0.09654266	10	0.80206134	0.389	Passed
VB_C2	0.890465	0.08375338	10	0.83055561	0.389	Passed
VB_C3	0.882984	0.07768781	10	0.82741335	0.389	Passed
VB_C4	0.847607	0.13488571	10	0.75112228	0.389	Passed
VB_C5	0.735888	0.25082081	10	0.55647407	0.389	Passed
VB_C6	0.662313	0.36427326	10	0.40174571	0.389	Passed
VB_C7	0.686772	0.36426675	10	0.42620937	0.389	Passed
VB_L1	0.7397	0.36842487	12	0.49912477	0.389	Passed
VB_L2	0.85353818	0.3119903	11	0.64075498	0.389	Passed
VB_L3	0.89139273	0.29651247	11	0.68916569	0.389	Passed
VB_L4	0.88930818	0.29491517	11	0.68817053	0.389	Passed
VB_L5	0.971761	0.01978041	10	0.95761193	0.389	Passed
VB_T01	0.749499	0.20357809	10	0.60387813	0.389	Passed
VB_T02	0.900861	0.10665309	10	0.82457127	0.389	Passed
VB_T03	0.846845	0.23384828	10	0.67957164	0.389	Passed
VB_T04	0.871065	0.16033768	10	0.7563743	0.389	Passed
VB_T05	0.868184	0.10527773	10	0.79287808	0.389	Passed
VB_T06	0.856586	0.1735606	10	0.73243685	0.389	Passed
VB_T07	0.895207	0.09111821	10	0.83002949	0.389	Passed
VB_T08	0.90946273	0.09927246	11	0.84175706	0.389	Passed
VB_T09	0.895233	0.19379417	10	0.75661063	0.389	Passed
VB_T10	0.85180692	0.25673522	13	0.69073999	0.389	Passed
VB_T11	0.90543538	0.17253913	13	0.79719022	0.389	Passed
VB_T12	0.73466077	0.38432697	13	0.49354712	0.389	Passed
VBs	0.984448	0.01042268	10	0.97699258	0.579	Passed
V_Venacava_I	0.95366786	0.05427303	14	0.92085737	0.72	Passed
V_Venacava_S	0.851219	0.0503676	10	0.81519069	0.8	Passed

Structure	Limbus Mean DSC	Limbus DSC Std Dev	Number of Scans	Limbus DSC lower 95% conf edge	Test DSC Threshold	Result
Vagina	0.897341	0.06081143	10	0.85384215	0.665	Passed
Ventricle_L	0.951144	0.00689877	10	0.94620926	0.9	Passed
Ventricle_R	0.980784	0.01685223	10	0.96872948	0.8	Passed
Wire_Breast_L (beta)	0.750245	0.28619472	10	0.54552785	0.39	Passed
Wire_Breast_R (beta)	0.896053	0.15011288	10	0.78867618	0.39	Passed

Mechanical and Acoustic Testing
Not Applicable (Standalone Software)

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

Clinical Studies
Clinical testing was not required to demonstrate the safety and effectiveness of Limbus Contour. Instead, substantial equivalence is based upon benchtop performance testing.

VIII. CONCLUSIONS
The minor differences between the subject Limbus Contour software and the predicate Limbus Contour software do not constitute a different intended use. The technological characteristics of the Limbus Contour software are similar to those of the predicate Limbus Contour software.

Results of software verification and validation testing demonstrate that the Limbus Contour software performs in accordance with specifications and that the performance is comparable to that of the predicate device. Therefore, the Limbus Contour software can be found to be substantially equivalent to the predicate Limbus Contour software device.