Limbus AI Inc.
% Mary Vater
510(k) Consultant
Medical Device Academy
345 Lincoln Hill Rd
SHREWSBURY VT 05738

April 7, 2023

Re: K230575
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: LLZ
Dated: March 1, 2023
Received: March 29, 2023

Dear Mary Vater:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.04.07 20:09:21 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230575

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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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.
2076 Athol Street
Regina, Saskatchewan, Canada, S4T3E5
Tel: 1-306-502-5982

Contact Person: Mary Vater
Email: mary@fdaecopy.com
Date Prepared: February 28, 2023

II. DEVICE

Name of Device:	Limbus Contour
Classification Name:	Radiological Image Processing System
Regulation:	21 CFR §892.2050
Regulation Name:	Medical image management and processing system
Regulatory Class:	Class II
Product Classification Code:	LLZ

III. PREDICATE DEVICE

Predicate Manufacturer:	Limbus AI, Inc.
Predicate Trade Name:	Limbus Contour
Predicate 510(k):	K201232

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 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.

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 were validated using an automatic contouring test to ensure the contours were accurate.

	Limbus Contour v1.7	Limbus Contour v1.1 - K201232	Similarities / Differences
Classification Regulation	892.2050 – Picture Archiving and Communication System	892.2050 – Picture Archiving and Communication System	Same
Product Code	LLZ	LLZ	Same

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 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 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.	Same

	Limbus Contour is not intended for use with digital mammography.	Limbus Contour is not intended for use with digital mammography.	Same
Intended User	Healthcare providers	Healthcare providers	Same
Contouring Modes	Automatic	Automatic	Same
Measurements	No measurement function.	No measurement function.	Same.

Image Fusion	No fusion support.	No fusion support.	Same
3D image rendering	No image rendering function.	No image rendering function.	Same
Image Modalities	CT and MR	CT and MR	Same
Platform	Stand-alone package which operates on Microsoft Windows operating system operating system	Stand-alone package which operates on Microsoft Windows operating system and MacOS operating system	Limbus Contour v1.7 does not support MacOS operating system
Environment of Use	Healthcare environment	Healthcare environment	Same

Materials	N/A – Standalone Software	N/A – Standalone Software	Same
Energy Source	N/A – Standalone Software	N/A – Standalone Software	Same
Feature Comparison: • Operating System • Hardware Requirements • Etc.	Operating System • Windows 10 / Windows Server 2016 and Above Hardware Requirements • 2 GHz or faster multi-core processor • 8 GB of RAM • For GPU versions, a CUDA capable NVIDIA GPU is required	Operating System • Windows 10 / Windows Server 2016 • Mac OS 10.14 Hardware Requirements • 2 GHz or faster multi-core processor • 4 GB of RAM • For GPU versions, a CUDA capable NVIDIA GPU is required	Limbus Contour v1.7 does not support MacOS operating system. RAM requirements are increased to 8GB in Limbus Contour v1.7
Performance Testing	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	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	Same

	software meets user needs and intended uses and to support substantial equivalence: • Automatic Contouring – Validation Test	substantial equivalence: • Automatic Contouring – Validation Test	
Structures available for automatic contouring	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 Bladder Body Bone_Hyoid Bone_Ilium Bone_Ilium_L Bone_Ilium_R Bone_Mandible Bowel Bowel_Extend Bowel_Full Bowel_S BrachialPlex_L BrachialPlex_R BrachialPlexs Brain Brainstem Brainstem Breast_L Breast_R Breasts Bronchus Canal_Anal CaudaEquina Cavity_Oral Chestwall Chestwall_L Chestwall_R Clavicle_L Clavicle_R Cochlea_L Cochlea_R	A_Aorta Bladder Brain BrainStem LN_Neck_L LN_Neck_R Esophagus Femur_Head_L Femur_Head_R Globe_L Globe_R Heart Glnd_Lacrimal_L Glnd_Lacrimal_R Lens_L Lens_R Lung_L Lung_R Mandible OpticNrv_L OpticNrv_R Parotid_L Parotid_R Prostate Rectum Glnd_Submand_L Glnd_Submand_R SpinalCord Trachea	Limbus Contour v1.7.0 contains new structures for automatic contouring

	Colon_Sigmoid Cornea_L Cornea_L Cornea_R Cornea_R Cricoid Duodenum Esophagus Eye_L Eye_L Eye_R 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_L Hippocampus_R Hippocampus_R Humerus_L Humerus_R Kidney_L Kidney_R Kidneys Larynx Lens_L Lens_R Lips Liver 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_Ax_Sclav_L LN_Ax_Sclav_R LN_IMN_L LN_IMN_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_L LN_Neck_R LN_Neck_V_L LN_Neck_V_R LN_Neck_VI LN_Neck_VIIAB_L LN_Neck_VIIAB_R LN_Pelvics LN_Sclav_L LN_Sclav_R Lung_L Lung_R Lungs Musc_Constrict Musc_PecMinor_L Musc_PecMinor_R Musc_Sclmast_L Musc_Sclmast_R OpticChiasm OpticNrv_L OpticNrv_R Optics Pancreas Parotid_L Parotid_R PelvisVessels PenileBulb PenileBulb Pituitary Prostate Prostate Prostate + SeminalVes PubicSymphys Rectum Rectum Retina_L Retina_L Retina_R Retina_R Ribs		

	Ribs_L Ribs_R Sacrum SeminalVes SeminalVes Skin SpinalCanal SpinalCord Spleen Sternum Stomach Trachea Uterus_Cervix V_Venacava_I V_Venacava_S Vagina Ventricle_L		

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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a moderate level of concern.

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

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 in indications of use 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.