Limbus AI Inc.   August 13, 2020
℅ Ms. Mary Vater
510(k) Consultant
Medical Device Academy
245 Lincoln Hill Road
SHREWSBURY VT 05738

Re: K201232
    Trade/Device Name: Limbus Contour
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: Class II
    Product Code: LLZ
    Dated: July 17, 2020
    Received: July 17, 2020

Dear Ms. 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
   and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K201232

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.

Limbus Contour is not intended to automatically contour tumors or tumor clinical target volumes.

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.

510(k) SUMMARY   K201232

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
Date Prepared: May 1, 2020

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: LLZ

III. PREDICATE DEVICE
Predicate Manufacturer: Microsoft Corp.
Predicate Trade Name: Radiomics App v1.0
Predicate 510(k):   K173420

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.

Limbus Contour is not intended to automatically contour tumors or tumor clinical target volumes.

VI.   COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

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 additional indications specific to tumor and organ contouring, whereas the subject device is not specifically indicated for that purpose.
- 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.
- Other Design Features – The contours generated from Limbus Contour are edited in external treatment planning or contouring tools and it does not contain an image viewer, whereas the predicate has these features integrated. The subject device also does not perform image fusion or subsequent contouring of fused images, or 3D image rendering, which are not necessary to achieve the intended use. Both devices are offered as a stand-alone package that operate on Microsoft Windows operating system. Limbus Contour also functions on a Mac OS.
- Performance Testing – The predicate and subject device were both were validated using an automatic contouring test to ensure the contours were accurate.

	Limbus AI	Radiomics App v1.0 – K173420	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.	Microsoft Radiomics App v1.0 is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal organ and tumor contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. Radiomics App assists in the following scenarios: • Load, save and display of medical images and contours for treatment evaluation and treatment planning. • Creation, transformation, and modification of contours for	Indications for use are similar other than the device not displaying medical images and contours. Related to that difference; the device is also not capable of fusing compatible images for treatment planning or three-dimensional rendering of medical

	• 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. Limbus Contour is not intended to automatically contour tumors or tumor clinical target volumes.	applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy, and archiving contours for patient followup. • Localization and definition of both solid tumors and healthy anatomical structures. • Fusion display of compatible images for treatment planning. • Three-dimensional rendering of medical images and the segmented contours. Images reviewed using the Radiomics App software should not be used for primary image interpretations. Radiomics App is not for use with digital mammography.	images and segmented contour. Unlike the predicate device, the Limbus Contour does not display images, and therefore it cannot be used for "primary image interpretations" so that is not included in the Limbus Contour indications. In addition, the device only localizes and defines healthy anatomical structures (not solid tumors like the predicate device).
Intended User	Healthcare providers	Healthcare providers	Same
Contouring Modes	Automatic	Assisted and Automatic	Contours generated from Limbus Contour are edited in external treatment-planning or contouring tools.
Measurements	No measurement function.	2D distance measurement, average tissue density within a region (for CT), segmentation volume	Limbus Contour does not contain an image viewer. No measurement functionality is provided because of this. These

			measurements are not necessary to achieve intended use.
Image Fusion	No fusion support.	Fuse only two 3D images, CT and MR	Limbus Contour does not perform image fusion and subsequent contouring on fused images. Not necessary to achieve intended use.
3D image rendering	No image rendering function.	Yes	Limbus Contour does not contain a viewer. Images are rendered in a separate viewing tool.
Image Modalities	CT and MR	CT and MR	Same
Platform	Stand-alone package which operates on Microsoft Windows operating system and MacOS operating system	Stand-alone package which operates on Microsoft Windows operating system only.	Limbus Contour will also support Mac OS operating systems
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 • 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	• Not specified.	
Performance Testing	Two different types of verification testing were conducted to verify the software requirements:	Two different types of verification testing were conducted to verify the software requirements:	Rendering and measurement tests are not applicable for the subject

	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	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 Radiomics App demonstrated that the software meets user needs and intended uses and to support substantial equivalence: • Measurements - Validation Test • Volumetric Rendering – Validation Test • Multi-Planar Reconstruction – Validation Test • Assisted Contouring – Validation Test • Automatic Contouring – Validation Test	device because it does not have those functions.

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 major 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 Radiomics software do not constitute a different intended use. The technological characteristics of the Limbus Contour software are similar to those of the Radiomics App. 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 Radiomics App software device.