April 8, 2022

Carina Medical LLC
℅ Xue Feng
Chief Executive Officer
1233 Litchfield Ln
Lexington, KY 40513

Re: K212274
Trade/Device Name: INT Contour
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ, QKB
Dated: July 20, 2021
Received: July 20, 2021

Dear Xue Feng:

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 and Part 809); 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,

Julie Sullivan, Ph.D.
Assistant Director
Nuclear Medicine and Radiation Therapy
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212274

Device Name
INTContour

Indications for Use *(Describe)*
INTContour provides a machine learning-based approach for the automatic segmentation of structures including treatment targets and organs at risk to support the radiation therapy treatment planning process. INTContour is intended as an initial method to segment and contour study series; therefore, this software must be used in conjunction with an appropriate software to edit the segmentation results if necessary. It is not intended to replace a thorough review by qualified medical professionals. INTContour is developed for use by dosimetrists, medical physicists, and radiation oncologists. The currently supported anatomical regions for automatic segmentation are head and neck, thorax, abdomen, and male pelvis.

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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CARINA

Innovative and Intelligent

Summary 510(k)

1. Applicant:

Carina Medical LLC

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Lexington, KY, 40513

USA

Contact Name: Xue Feng – Chief Executive Officer

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E-mail: xfeng@carinaai.com

2. Device:

Trade Name: INTContour

Common Name: Intelligent Organ Contouring System

Model Number: v1.0

Product Code: MUJ

Regulation Description: Medical charged-particle radiation therapy system

Regulation Number: 21 CFR 892.5050

Device Class: II

3. Predicate Devices:

Trade Name: Smart Segmentation – Knowledge Based Contouring

Manufacturer: Varian Medical Systems, Inc.

Address: 3100 Hansen Way, Palo Alto, CA, 94303

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Device Class: II

Product Code: MUJ

510(k) Number: K141248

510(k) Clearance Date: 09/05/2014

4. Reference Device:

Trade Name: AccuContour

Manufacturer: Xiamen Manteia Technology LTD.

Address: 1903, B Tower, Zijin Plaza, No.1811 Huandao East Road, Xiamen, China

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Device Class: II

Product Code: QKB

510(k) Number: K191928

510(k) Clearance Date: 02/28/2020

5. Device Description

INTContour is a software-only product that uses a machine learning-based approach to perform automatic segmentation of structures in medical images, coupled with tools for visualizing the segmentation results. A library of previously contoured expert cases serves as inputs to train the machine learning algorithms, specifically, convolutional neural networks (CNNs), to perform

automatic segmentation. The results of the automatic segmentation will be stored in the DICOM Radiotherapy Structure Set (RTSTRUCT) format, which can be sent to desired destinations via the DICOM protocol.

INTContour is intended to be used by dosimetrists, medical physicists, and radiation oncologists, and serves as an initial method to segment and contour study series. It must be used in conjunction with appropriate software to edit the segmentation results if necessary. The currently supported anatomical regions for automatic segmentation are head and neck, thorax, abdomen, and male pelvis. The supported structures for each region are shown below in section 10.

INTContour software is intended to be deployed within a hospital's private network on a workstation with an advanced graphics processing unit (GPU) and runs as a service. A web-based interface is used to access the service and manage the transfer of data, automatic segmentation, and visualization.

6. Intended Use Statement

INTContour provides a machine learning-based approach for automatic segmentation of structures including treatment targets and organs at risk to support the radiation therapy treatment planning process.

7. Indications for Use Statement

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automatic segmentation are head and neck, thorax, abdomen, and male pelvis. The supported structures for each region are shown below in Section 10.

8. Summary of Technological Characteristics Comparison

Table 1 shows the similarities and differences between the technological characteristics of the two products. The key difference is the detailed implementation of the automated segmentation algorithms. Testing demonstrates that the differences do not raise new questions of safety or effectiveness.

Table 1. Summary of Technological Characteristic Comparison

Topic	**Predicate Device**	**Subject Device**
Physical Characteristics	Software package that operates on off-the-shelf hardware	Software package that operates on a virtual machine within the off-the-shelf hardware
Computer	PC Compatible	Same
Operating System	Windows	Ubuntu (18.04 & 20.04)
DICOM Standard Compliance	The software processes DICOM compliant image data, including RTSTRUCT	Same
Modalities	CT & MRI	Same
User Interface	The software is designed for use on a radiotherapy workstation with a native user interface.	The software is designed for use on a radiotherapy workstation with a web-based user interface
Segmentation Structures	Organs at risk and target volumes	Same

Overall Segmentation Method	Model-based approach using a library of expert contours	Same
Detailed Implementation of Segmentation Algorithm	Smart Segmentation – knowledge-based contouring used an atlas-based method to deform expert contours to the target images to generate contours	INTContour used a machine learning-based method to train CNNs from expert contours to perform segmentation on the target images to generate contours
Support of Manual Editing	Yes	No
Provide Expert Case Library to Users	Yes	No

9. Performance Data

The safety and performance of INTContour has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Non-clinical verification and validation test results, including model performance and software usability, established that the device meets its design requirements and intended use, that it is as safe and as effective as the predicate devices, and that no new issues of safety and effectiveness were raised.

Testing data was acquired from multiple sources than the training data that covers head and neck, thorax, abdomen, and male pelvis regions. The cases were selected from patients who went through radiation treatment with age 18 – 76, both male and female and various types of cancers. Ground truth was performed by at least two trained personnel including dosimetrist, medical physicist and/or radiation oncologist to minimize human bias in segmentation.

Further, during the development, potential hazards were controlled by a risk management plan including risk analysis, risk mitigation, verification and validation.

10. Results

The Dice metric and 95% Hausdorff Distance (HD95) were calculated for each organ. Statistical analysis on the test data was performed by comparing the calculated metrics of INTContour against the predicate/reference device. Dice metric was used for large organs and HD95 was used for small organs to define the acceptance criteria due to the large variations on Dice metric on small organs. By comparing the lower bound (Dice) or upper bound (HD95) of the performance differences between INTContour and the predicate/reference device with the threshold values, all organs have passed the acceptance criteria and demonstrated the non-inferiority against the predicate/reference device.

The table below shows the list of all supported organs:

Head and Neck		**Thorax**	**Abdomen**	**Male Pelvis**
Brainstem	Pituitary	SpinalCanal	Spleen	Bladder
OpticChiasm	InnerEar_L	Lung_R	Kidney_R	Femur_Head_L
Bone_Mandible	InnerEar_R	Lung_L	Kidney_L	Femur_Head_R
OpticNrv_L	Lens_L	Heart	Gallbladder	PenileBulb
OpticNrv_R	Lens_R	Esophagus	Esophagus	Prostate
Parotid_L	Lobe_Temporal_L	Trachea	Liver	SeminalVesicle
Parotid_R	Lobe_Temporal_R	BronchialTree	Stomach	Rectum
Glnd_Submand_L	Larynx	SpinalCord	A_Aorta	
Glnd_Submand_R	Cavity_Oral		V_Venacava_I	
Eye_L	Pharynx		PortalVein	

Eye_R	Brain		Pancreas	
MidEar_L	Cochlea_L		AdrenalGland_R	
MidEar_R	Cochlea_R		AdrenalGland_L	
Joint_TM_L	Glnd_Lacrimal_L		SplenicVein	
Joint_TM_R	Glnd_Lacrimal_R			
BrachialPlex_L	BrachialPlex_R			

11. Substantial Equivalence Conclusion

INTContour is an automatic segmentation software to support the radiation treatment planning process which has similar intended use and indications for use statement as the predicate device. The two devices have similar technological characteristics: both algorithms rely on a library of expert contours and use model-based approach to generate contours on new images. This 510(k) submission includes information on the INTContour technological characteristics, as well as performance data and verification and validation activities demonstrating that INTContour is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness.