MVision AI
Kalpana Jha
Quality and Compliance Manager
C/O Terkko Health Hub
Haartmaninkatu 4
Helsinki, 00290
FINLAND

May 3, 2022

Re: K212915
Trade/Device Name: MVision AI Segmentation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: March 29, 2022
Received: April 1, 2022

Dear Kalpana Jha:

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,

Michael O'Hara, Ph.D.
Deputy Director
Division of Radiological Imaging and Radiation Therapy
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212915

Device Name
MVision AI Segmentation

Indications for Use *(Describe)*
MVision AI Segmentation is a software system for image analysis algorithms to be used in radiation therapy treatment planning workflows. The system includes processing tools for automatic contouring of CT images using machine learning based algorithms. The produced segmentation templates for regions of interest must be transferred to appropriate image visualization systems as an initial template for a medical professional to visualize, review, modify and approve prior to further use in clinical workflows.

The system creates initial contours of pre-defined structures of common anatomical sites, i.e. Head and Neck, Brain, Breast, Lung and Abdomen, Male Pelvis, and Female Pelvis in adult patients.

MVision AI Segmentation is not intended to detect lesions or tumors. The device is not intended for use with real-time adaptive planning workflows.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Below mentioned information is provided as required by 21 CFR 807.92

Submitter's Information

Name and Address	MVision AI C/O Terkko Health Hub Haartmaninkatu 4 00290 Helsinki Finland Tel: +358 (0) 40 5489 229 info@mvision.ai
Primary Contact Person	Kalpana Jha Quality and Compliance Manager kalpana.jha@mvision.ai Tel: +358 44 9214 354

Subject Device

Subject Device	**MVision AI Segmentation**, New Software Medical Device
Trade Name	MVision Segmentation Service
Common Name	Medical Image Segmentation Software
Product Code and Classification	Medical image management and processing system. QKB | 21 CFR §892.2050 | Class II Medical Device

Predicate Device

Predicate Device - **Mirada Workflow Box**, Software Medical Device (**K181572**)

This predicate has not been subject to a design-related recall.

Device Description

MVision AI Segmentation is a software only medical device which can be used to accelerate region of interest (ROI) delineation in radiotherapy treatment planning by creating automatic segmentation templates on CT images for these ROIs.

The segmentations are produced by pre-trained, locked, and static models that are based on deep artificial neural networks. The produced structure is intended to be used as a template for medical professionals to visualize, modify and approve prior to further use in clinical workflows.

The system is integrated with the customer IT network to receive DICOM images. CT images from, for example, a scanner or a treatment planning system (TPS) are exported to the device. A structure set is created in the device, and the created segmentation results are connected to the original images. These data are sent to the destination DICOM import folder to import the data to, for example, a treatment planning system. The produced structures can then be used as a template for manual ROI editing, review

and approval workflow. The segmentations are produced by pre-trained and locked models that are based on deep artificial neural networks. To take the device into use, the user does not have to provide any contouring atlases. The models have been trained with the order of hundreds of scans, depending on the ROI in question. The MVision AI Segmentation device creates initial contours of pre-defined structures of common anatomical sites, i.e. Head and Neck, Brain, Breast, Lung and Abdomen, Male Pelvis, and Female Pelvis. Supported anatomical sites and ROI listing of the organs for which the device creates initial contours for, are listed below:

Lung and Abdomen	Brain	Breast
A_Aorta	Body	A_Aorta
A_LAD	Brain	A_Carotid_R/L
Body	Brainstem	A_LAD
Bowel_Large	Cochlea_R/L	Body
Bowel_Small	Eye_Ant_R/L	BrachialPlex_R/L
BrachialPlex_R/L	Eye_Post_R/L	Breast_R/L
Bronchus_Prox	Eye_R/L	Glnd_Thyroid
Chestwall_R/L	Glnd_Lacrimal_R/L	Heart
Esophagus	Lens_R/L	Humerus_R/L
Heart	OpticChiasm	LN_Axillary_R/L
Heart+A_Pulm	OpticChiasm_cnv	LN_Breast_L1_R/L
Kidney_R/L	OpticNrv_R/L	LN_Breast_L2_R/L
Liver	OpticNrv_cnv_R/L	LN_Breast_L3_R/L
Lung_R/L	Pituitary	LN_Breast_L4_R/L
Pancreas		LN_IMN_IC4_R/L
SpinalCanal		LN_IMN_R/L
SpinalCord		LN_Intpect_R/L
Spleen		Lung_R/L
Stomach		SpinalCanal
Trachea		SpinalCord
Trachea_Prox		Trachea
V_Venacava_I		V_Venacava_I
V_Venacava_S		

510(k) Summary

Female Pelvis	Head and Neck	Male Pelvis
Bag_Bowel	A_Carotid_R/L	A_Aorta
Bladder	Arytenoid_R/L	Bag_Bowel
Body	Body	Bladder
Bone_Pelvic	Bone_Mandible	Body
Bowel_Large	BrachialPlex_R/L	Bone_Pelvic
Bowel_Small	Brain	Bowel_Large
Femur_R/L	Brainstem	Bowel_Small
Kidney_R/L	Buccal_Mucosa_R/L	Femur_R/L
L4_VB	Cavity_Oral	Kidney_R/L
L5_VB	Cochlea_R/L	L4_VB
Rectum	Cricophar_inlet	L5_VB
Sacrum	Esophagus_S	LN_Pivotal
SpinalCanal	Eye_Ant_R/L	LN_RTOG
UteroCervix	Eye_Post_R/L	Markers
	Eye_R/L	Musc_Coccygeus_R/L
	Glnd_Lacrimal_R/L	Musc_Iliacus_R/L
	Glnd_Submand_R/L	Musc_Obt_Int_R/L
	Glnd_Thyroid	Musc_Pirifor_R/L
	Glottis	Musc_Psoas_Maj_R/L
	LN_Neck_IA	PenileBulb
	LN_Neck_IB_R/L	Prostate
	LN_Neck_III_R/L	Rectum
	LN_Neck_II_R/L	Sacrum
	LN_Neck_IVA_R/L	SeminalVes
	LN_Neck_IVB_R/L	V_Venacava_I
	LN_Neck_IX_R/L	Vessels_Long_R/L
	LN_Neck_VC_R/L	Vessels_R/L
	LN_Neck_VIA	
	LN_Neck_VIB	
	LN_Neck_VIIA_R/L	
	LN_Neck_VIIB_R/L	
	LN_Neck_V_R/L	
	LN_Neck_XA_R/L	
	LN_Neck_XB_R/L	
	Larynx_SG	
	Lens_R/L	
	Lips	
	Lung_R/L	
	Musc_Constrict	
	OpticChiasm	
	OpticChiasm_cnv	
	OpticNrv_R/L	
	OpticNrv_cnv_R/L	
	Parotid_R/L	
	Pituitary	
	SpinalCanal	
	SpinalCord	
	Trachea	

510(k) Summary

The MVision AI Segmentation software has two deployment modes and is written in a way that allows running the same code in two different environments:

On-premises (local): For the local Healthcare environment, DICOM image and structure set data is transferred via the DICOM TCP/IP protocol for subject device and predicate device.

Cloud: For the cloud environment, de-identified DICOM image and structure set data is transferred via secure HTTPS protocol and HTTPS data is protected by TLS encryption for the subject device.

Indication for use / Condition of use

MVision AI Segmentation is a software system for image analysis algorithms to be used in radiation therapy treatment planning workflows. The system includes processing tools for automatic contouring of CT images using machine learning based algorithms. The produced segmentation templates for regions of interest must be transferred to appropriate image visualization systems as an initial template for a medical professional to visualize, review, modify and approve prior to further use in clinical workflows.

The system creates initial contours of pre-defined structures of common anatomical sites, i.e. Head and Neck, Brain, Breast, Lung and Abdomen, Male Pelvis, and Female Pelvis in adult patients.

MVision AI Segmentation is not intended to detect lesions or tumors. The device is not intended for use with real-time adaptive planning workflows.

Intended Use

MVision AI Segmentation is a software system for image analysis algorithms to be used in radiation therapy treatment planning workflows. The system includes processing tools for automatic contouring of CT images using machine learning based algorithms. The produced segmentation templates for regions of interest must be transferred to appropriate image visualization systems as an initial template for a medical professional to visualize, review, modify and approve prior to further use in clinical workflows.

MVision AI Segmentation is not intended to detect lesions or tumors. The device is not intended for use with real-time adaptive planning workflows.

Comparison Summary of Intended use with Predicate device

MVision AI Segmentation and the predicate device are identical with regard to intended use; specifically, for automatic contouring of imaging data to be used in radiotherapy treatment planning workflows. Both the subject and predicate devices are software only medical devices and output contours of both medical devices are intended to be visualized, edited as appropriate and approved by trained medical professionals for further use in clinical workflows. The review and editing of contouring results from both the subject and predicate devices can be performed using different image visualization systems. Both the subject and predicate devices are not intended to be used for automatic diagnosis of disease. Therefore, the intended use of the subject device **MVision AI Segmentation** is substantially equivalent to the predicate device **Workflow Box**.

510(k) Summary

Comparison of Technological Characteristics with Predicate Device

MVision AI Segmentation has similar technological characteristics as the predicate device. Automated segmentation of the patient anatomy is the technological principle for both the subject and predicate devices.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both devices are software only medical devices
- Both devices include automatic segmentation algorithms to process radiological images in order to produce contouring of human anatomical regions
- Both devices are intended to be used by trained medical professionals
- Both the subject and the predicate device is not intended to be used for automatic diagnosis of disease
- Output contours of both devices are intended to be visualized, modified and approved by a medical professional for further use in clinical workflows
- Both the predicate and the subject device do not inherently contain material as they are software-only devices

The following technological differences exist between the subject and predicate devices.

- ***MVision AI Segmentation*** is intended for automatic contouring of imaging data using machine learning based algorithms whereas predicate device offers automatic contouring of imaging data using both atlas based deformable image registration as well as machine learning algorithm.

- Subject device ***MVision AI Segmentation*** is operated either by the manufacturer in the manufacturer's cloud or by a healthcare provider in the healthcare provider's IT network. Predicate device Workflow Box can be operated only in a healthcare provider's IT network.

Performance data

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. Verification and Validation for MVision AI Segmentation has been carried out in compliance with the requirements of CFR 21 Part 820 and in adherence to the DICOM standard.

Software verification and validation, performance evaluation for machine learning based algorithms, and implemented Cybersecurity control measures and tests establish that the subject medical device is safe, secure and effective for its user needs and defined intended use.

No animal studies or clinical tests have been included in this pre-market submission.

Performance Evaluation Summary

Training and test sets (golden dataset) were collected and created to include high granularity in performance evaluation tests. They originate from multiple different sources to make sure the evaluated

model performance will reflect the real clinical performance in any radiotherapy clinic following the segmentation consensus guidelines the models are trained to comply with.

Performance verification results for various subsets of the golden dataset show the generalizability and robustness of the device for the US patient population and US medical practice. Furthermore, Performance Validation results for machine learning based algorithms carried out by radiotherapy experts show that MVision AI Segmentation assists in reducing the upfront effort and time on typical contouring which can be spent on refining and reviewing the results. Performance validation data further suggests that the subject device produces usable contours (ROIs) as a starting point that will save clinicians' time and it will lead to sooner proceeding to essential parts of radiotherapy treatment planning stages.

Conclusion

The intended use of the subject device MVision AI Segmentation is substantially equivalent to the predicate device Mirada Workflow Box. MVision AI Segmentation has similar technological characteristics as the predicate device and differences in technological characteristics do not raise different questions of safety and effectiveness.

Software verification and validation and Performance evaluation tests for machine learning based algorithms establish that the subject medical device is non-inferior, performs safely and effectively as the listed predicate device.

Hence, MVision AI Segmentation is substantially equivalent to the predicate device Mirada Workflow Box.