MVision AI Oy
Kalpana Jha
VP of Regulatory and Market Strategy
Paciuksenkatu 29, 6th Floor
Helsinki, 00270
Finland

October 18, 2024

Re: K241490
Trade/Device Name: Contour+ (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: June 25, 2024
Received: September 24, 2024

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 (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)*

K241490

Device Name

Contour+ (MVision AI Segmentation)

Indications for Use *(Describe)*

Contour+ (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 and MR 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.

Contour+ (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 – K241490

The following information is provided as required by 21 CFR 807.92

Date Prepared: June 25, 2024

## Submitter's Information


Company Name and Address: MVision AI Oy
Paciuksenkatu 29, 6th floor
00270 Helsinki, Finland
Tel: +358 (0) 40 721 3783
info@mvision.ai

Establishment Registration Number: 3022745617

Contact Person: Kalpana Jha
VP of Regulatory and Market Strategy
kalpana.jha@mvision.ai
Tel: +358 44 9214 354


## Subject Device

| | |
|---|---|
| Device Trade Name: | **Contour+** (MVision AI Segmentation) |
| Common Name: | Medical Image Segmentation Software |
| Device Classification Name: | Radiological Image Processing Software For Radiation Therapy |
| Product Code: | QKB |
| Device Class: | Class II |
| Review Panel: | Radiology |
| Regulation Description: | Medical Image Management And Processing System |
| Regulation Number: | 21 CFR §892.2050 |

## Predicate Device

| | |
|---|---|
| Device Name: | MVision AI Segmentation |
| 510(k) Number: | K212915 |
| Manufacturer: | MVision AI Oy |

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

## Device Description

**Contour+** (MVision AI Segmentation) is a software-only medical device (software system) that can be used to accelerate region of interest (ROI) delineation in radiotherapy treatment planning by automatic contouring of predefined ROIs and the creation of segmentation templates on CT and MR images.

The **Contour+** (MVision AI Segmentation) software system is integrated with a customer IT network and configured to receive DICOM CT and MR images, e.g., from a CT or MRI scanner or a treatment planning

system (TPS). Automatic contouring of predefined ROIs is performed by pre-trained, locked, and static models that are based on machine learning using deep artificial neural networks. The models have been trained on several anatomical sites, including the brain, head and neck, bones, breast, lung and abdomen, male pelvis, and female pelvis using hundreds of scans from a diverse patient population. The user does not have to provide any contouring atlases. The resulting segmentation structure set is connected to the original DICOM images and can be transferred to an image visualization system (e.g., a TPS) as an initial template for a medical professional to visualize, modify and approve prior to further use in clinical workflows.

The following is a listing of supported anatomical sites and ROIs of the organs for which the device creates initial contours:

| CT Bones | CT Breast | CT Head and Neck |
|---|---|---|
| C1 | A_Aorta | A_Carotid_L/R |
| C2 | A_Aorta_v2 | Arytenoid_L/R |
| C3 | A_Carotid_L/R | Body |
| C4 | A_LAD | Bone_Mandible |
| C5 | A_Pulm | BrachialPlex_L/R |
| C6 | Atrium_L/R | Brain |
| C7 | Bag_Bowel | Brainstem |
| L1 | Body | Buccal_Mucosa_L/R |
| L2 | Br_1234_RTOG_L/R | Cavity_Oral |
| L3 | Br_234_RTOG_L/R | Cochlea_L/R |
| L4 | BrachialPlex_L/R | Cricophar_inlet |
| L5 | Breast_L/R | Esophagus_S |
| Rib01_L/R | Breast_RTOG_L/R | Eye_Ant_L/R |
| Rib02_L/R | BrTW_1234_RTOG_L/R | Eye_Post_L/R |
| Rib03_L/R | BrTW_234_RTOG_L/R | Eye_L/R |
| Rib04_L/R | BrTW_RTOG_L/R | Glnd_Lacrimal_L/R |
| Rib05_L/R | Esophagus | Glnd_Submand_L/R |
| Rib06_L/R | Glnd_Thyroid | Glnd_Thyroid |
| Rib07_L/R | Heart | Glottis |
| Rib08_L/R | Heart+A_Pulm | LN_Neck_IA |
| Rib09_L/R | Humerus_Head_L/R | LN_Neck_IB_L/R |
| Rib10_L/R | Humerus_L/R | LN_Neck_III_L/R |
| Rib11_L/R | Liver | LN_Neck_II_L/R |
| Rib12_L/R | LN_Axilla_RTOG_L/R | LN_Neck_IVA_L/R |
| T1 | LN_Axillary_L/R | LN_Neck_IVB_L/R |
| T10 | LN_B_RTOG_L1_L/R | LN_Neck_IX_L/R |
| T11 | LN_B_RTOG_L2_L/R | LN_Neck_VC_L/R |
| T12 | LN_B_RTOG_L3_L/R | LN_Neck_VIA |
| T2 | LN_B_RTOG_L4_L/R | LN_Neck_VIB |
| T3 | LN_B_RTOG_L5_L/R | LN_Neck_VIIA_L/R |
| T4 | LN_Breast_L1_L/R | LN_Neck_VIIB_L/R |
| T5 | LN_Breast_L2_L/R | LN_Neck_V_L/R |
| T6 | LN_Breast_L3_L/R | LN_Neck_XA_L/R |

| | | |
|---|---|---|
| T7 | LN_Breast_L4_L/R | LN_Neck_XB_L/R |
| T8 | LN_IMN_IC4_L/R | Larynx_SG |
| T9 | LN_IMN_L/R | Lens_L/R |
| | LN_Intpect_L/R | Lips |
| | LN_RTOG_IMN_L/R | Lung_L/R |
| | Lung_L/R | Musc_Constrict |
| | SpinalCanal | OpticChiasm |
| | SpinalCord | OpticChiasm_cnv |
| | Spleen | OpticNrv_L/R |
| | Stomach | OpticNrv_cnv_L/R |
| | Trachea | Parotid_L/R |
| | V_Venacava_I | Pituitary |
| | V_Venacava_S | SpinalCanal |
| | Ventricle_L/R | SpinalCord |
| | Wire | Trachea |

| CT Lung and Abdomen | CT Female Pelvis | CT Male Pelvis |
|---|---|---|
| A_Aorta | A_Aorta | A_Aorta |
| A_Aorta_v2 | Bag_Bowel | Bag_Bowel |
| A_LAD | Bladder | Bladder |
| A_Pulm | Body | Body |
| Atrium_L/R | Bone_Pelvic | Bone_Pelvic |
| Bag_Bowel | Bowel_Large | Bowel_Large |
| Body | Bowel_Small | Bowel_Small |
| Bones | CTV_Central | CaudaEquina |
| Bowel_Large | CTV_Param | Duodenum |
| Bowel_Small | CTV_Pelvis | Femur_Head_L/R |
| BrachialPlex_L/R | Duodenum | Femur_Implant_L/R |
| Bronchus_Prox | Femur_Head_L/R | Femur_L/R |
| Chestwall_L/R | Femur_Implant_L/R | Kidney_L/R |
| Duodenum | Femur_L/R | L4_VB |
| Esophagus | Kidney_L/R | L5_VB |
| Heart | L4_VB | Liver |
| Heart+A_Pulm | L5_VB | LN_Inguinal_L/R |
| Humerus_Head_L/R | Liver | LN_NRG |
| Humerus_L/R | LN_Gyn_RTOG | LN_Pivotal |
| Kidney_L/R | LN_Inguinal_L/R | LN_RTOG |
| Liver | LN_PAN | Markers |
| Lung_L/R | LN_PAN_Long | Musc_Coccygeus_L/R |
| Pancreas | LN_Pivotal | Musc_Iliacus_L/R |
| SpinalCanal | LN_RTOG | Musc_Obt_Int_L/R |
| SpinalCord | Musc_Coccygeus_L/R | Musc_Pirifor_L/R |

| | | |
|---|---|---|
| Spleen | Musc_Iliacus_L/R | Musc_Psoas_Maj_L/R |
| Stomach | Musc_Obt_Int_L/R | Pancreas |
| Trachea | Musc_Pirifor_L/R | PenileBulb |
| Trachea_Prox | Musc_Psoas_Maj_L/R | Prostate |
| V_Venacava_I | Pancreas | RectoSigmoid |
| V_Venacava_S | RectoSigmoid | Rectum |
| Ventricle_L/R | Rectum | Sacrum |
| | Sacrum | SeminalVes |
| | SpinalCanal | SpinalCanal |
| | SpinalCord | SpinalCord |
| | Spleen | Spleen |
| | Stomach | Stomach |
| | UteroCervix | V_Venacava_I |
| | V_Venacava_I | Vessels_L/R |
| | Vagina | Vessels_Long_L/R |
| | Vessels_L/R | |
| | Vessels_Long_L/R | |

| CT Brain | MR Brain | MR T2 Male Pelvis |
|---|---|---|
| A_Carotid_L/R | Amygdala_L/R | Bladder |
| Body | Body | BladderTrigone |
| Brain | Brain | PenileBulb |
| Brainstem | Brainstem | Prostate |
| Cochlea_L/R | Cerebellum | Rectum |
| Eye_Ant_L/R | CorpusCallosum | SeminalVes |
| Eye_L/R | Eye_L/R | Spacer |
| Eye_Post_L/R | Glnd_Lacrimal_L/R | |
| Fossa_Pituitary | Hippocampus_L/R | |
| Glnd_Lacrimal_L/R | Hypothalamus | |
| Lens_L/R | MedullaOblongata | |
| OpticChiasm | Midbrain | |
| OpticChiasm_cnv | OpticChiasm | |
| OpticNrv_cnv_L/R | OpticChiasm_cnv | |
| OpticNrv_L/R | OpticNrv_cnv_L/R | |
| Parotid_L/R | OpticNrv_L/R | |
| Pituitary | OpticTract_cnv_L/R | |
| SpinalCanal | OpticTract_L/R | |
| SpinalCord | Pituitary | |
| | Pons | |
| | Thalamus_L/R | |

# 510(k) Summary – K241490

The **Contour+** (MVision Al Segmentation) software system 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.
- Cloud: For the cloud environment, de-identified DICOM image and structure set data are transferred via secure HTTPS protocol. HTTPS data is protected by TLS encryption.

## Indication for use / Intended use

**Contour+** (MVision Al 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 and MR 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.

**Contour+** (MVision Al Segmentation) is not intended to detect lesions or tumors. The device is not intended for use with real-time adaptive planning workflows.

## Comparison with the Predicate Device

**Contour+** (MVision AI Segmentation) is an incremental minor version release with the same intended use, indications for use, and principles of operation as the predicate software version.

The following table outlines the similarities and differences between the two software versions:

| | MVision AI Segmentation (K212915) | Contour+ (MVision Al Segmentation) | Comparison |
|---|---|---|---|
| Indications for 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.<br><br>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.<br><br>MVision AI Segmentation is not intended to detect lesions or tumors. The device is not intended for use with real-time adaptive planning workflows. | Contour+ (MVision Al 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 and MR 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.<br><br>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.<br><br>Contour+ (MVision Al Segmentation) is not intended to detect lesions or tumors. The device is not intended for use with real-time adaptive planning workflows. | Same intended use. The only difference is the inclusion of processing tools for automatic contouring of MR images, in addition to CT images – this is a change in technological characteristics that does not affect the intended use of the device. |

# 510(k) Summary – K241490

| | MVision AI Segmentation (K212915) | Contour+ (MVision Al Segmentation) | Comparison |
|---|---|---|---|
| Intended Users | Designed to be used by clinicians trained in radiation therapy workflows. | Designed to be used by clinicians trained in radiation therapy workflows. | Same. |
| Target Patient Population | Patients who have been prescribed radiation therapy. | Patients who have been prescribed radiation therapy. | Same |
| Deployment Environment | • Cloud based software Application<br>• Local (on customer premises) installation in healthcare provider's IT network / server | • Cloud based software Application<br>• Local (on customer premises) installation in healthcare provider's IT network / server | Same |
| Operating Platform | • Ubuntu | • Ubuntu<br>• Windows | Contour+ may also run in a Windows operating platform |
| Communications / Networking | DICOM image and structure set data transfers<br>• TCP/IP, SCP, and HTTP (Local)<br>• TCP/IP, SCP, and HTTPS (Cloud) | DICOM image and structure set data transfers<br>• TCP/IP, SCP, and HTTP (Local)<br>• TCP/IP, SCP, and HTTPS (Cloud) | Minor changes:<br>Added API script to send scans directly from the Varian Eclipse Treatment Planning System;<br>Provided read-only Import/Export UI to upload/download DICOM data via a web browser |
| Imaging modalities | • CT | • CT<br>• MR | Added support for automatic contouring of MR images |
| Segmentation algorithms | • Machine learning-based contouring using deep learning-based models<br>• Does not support segmentation based on atlas-based techniques | • Machine learning-based contouring using deep learning-based models<br>• Does not support segmentation based on atlas-based techniques | Same algorithms; Updated certain CT segmentation models; Added 1 CT and 2 MR models |
| Registration based re-contouring | No | No | Same |

The different technological characteristics of the two software versions do not raise different questions of safety and effectiveness.

- Both software versions are intended to accelerate region of interest delineation in radiological images by automatic contouring and the creation of segmentation templates to be used by qualified healthcare professionals in radiation therapy treatment planning workflows.
- Both software versions are not intended to detect lesions or tumors, and they are not intended for use with real-time adaptive planning workflows.
- Both software versions are intended to create initial contours of predefined structures of common anatomical sites, such as head and neck, brain, breast, lung and abdomen, male pelvis, and female pelvis on scans that are appropriate for treatment planning. The addition of a model to segment specifically bone structures on CT images and the addition of models for the segmentation of MR images does not change the device intended use and indications for use.
- Both software versions are intended to produce segmentation templates for regions of interest that 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.
- As radiotherapy treatment planning may be performed effectively using CT and/or MR images, automatic contouring for the creation of segmentation templates of predefined structures of anatomical regions of interest in images from either modality offers the same benefits and presents the same risks.
- In both software versions, automatic contouring of images (segmentation of anatomical regions of interest) is performed by pre-trained, locked, and static models that are based on machine learning using the same deep artificial neural networks. The segmentation algorithms remain the same.

## Performance data – Verification and Validation Testing

Verification and validation testing of this software release was also conducted as per FDA's Guidance for the "*Content of Premarket Submissions for Device Software Functions (2023)*," including compliance with recognized consensus standards (e.g., IEC 62304, IEC 62366-1, ISO 14971, DICOM) and FDA guidance for "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023)*," and "*Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (2017)*."

Device performance with the updated CT models and the additional CT and MR models, i.e., the effectiveness of the automatic segmentation methods (machine learning-based models) in the modified software version, was evaluated using the same data management practices (including data sources, sample size, and model generalizability) and established test protocols as previously reviewed by the FDA.

The training and the test (golden) datasets were chosen to achieve high granularity in performance evaluation tests. The datasets originate from multiple EU and US clinical sites (with over 50% of data coming from US sites) with a broad diversity of patients and medical imaging technology that are deemed representative of the US population and medical practice. This also ensures that the evaluated model performance reflects the real clinical performance in any radiotherapy clinic following the segmentation consensus guidelines the models are trained to comply with.

The performance of both CT and MR automatic segmentation models was evaluated by comparing the produced auto-segmentations to ground truth segmentations and calculating similarity scores DSC (Dice Score) and S-DSC@2mm (Surface-Dice Score) for all regions of interest (ROI). The ROI acceptance criteria are based on a set level of minimum agreement against ground truth segmentations determined through clinically relevant similarity metrics DSC and S-DSC@2mm.

Performance verification and validation 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.

Performance validation of machine learning-based algorithms for automatic segmentation was also carried out by radiotherapy experts. The results show that Contour+ (MVision AI Segmentation) assists in reducing the upfront effort and time required for contouring CT and MR images, which can instead be devoted by clinicians on refining and reviewing the software-generated contours.

The additional functional interoperability changes (the API script for the Varian Eclipse TPS, and the Import/Export UI) and the labeling change to support deployment of the software on a Windows operating platform do not have an impact on device safety or effectiveness. Successful software execution in a Windows operating environment and the functional interoperability changes was performed using the same established design verification test protocols as for the predicate software version per Product Life Cycle Procedure, based on FDA recognized consensus standards and design control regulation 21 CFR 820.30.

## Conclusion

**Contour+** (MVision AI Segmentation) is an incremental minor version release with the same intended use, indications for use, and principles of operation as the predicate software version. The different technological characteristics of the two software versions do not raise different questions of safety and effectiveness. Software verification and validation testing, including the performance of all CT and MR models using established protocols and recognized standards demonstrate that **Contour+** (MVision AI Segmentation) fulfills the same acceptance criteria, provides the intended benefits, and it is as safe and as effective as the predicate software version (MVision AI Segmentation).