U.S. FOOD & DRUG ADMINISTRATION

RaySearch Laboratories AB (publ)
℅ David Hedfors
Quality and Regulatory Affairs Director
Eugeniavagen 18
Stockholm, 113 68
SWEDEN

March 29, 2023

Re: K222312
Trade/Device Name: RayStation 12A
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: July 26, 2022
Received: August 1, 2022

Dear David Hedfors:

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: 2023.03.29 10:20:55 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222312

Device Name
RayStation 12A

Indications for Use *(Describe)*

RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

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.

1. 510(k) Summary

1.1 510(k) owner

RaySearch Laboratories AB (publ)
Eugeniavägen 18
113 68 Stockholm
Sweden

Tel: +46 8 510 530 00

1.2 Contact person

David Hedfors
Quality and Regulatory Affairs Director
RaySearch Laboratories AB (publ)
Email: quality@raysearchlabs.com
Tel: +46 722 366 110

1.3 Preparation date

March 28th, 2023.

1.4 Trade name

The trade name is RayStation.

The marketing name is RayStation 12A and RayPlan 12A.

1.5 Common name

Radiation therapy treatment planning system

1.6 Classification name

Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code MUJ)

1.7 Predicate device

K220141 RayStation 11B

1.8 Device description

RayStation is a treatment planning system for planning, analysis and administration of radiation therapy and medical oncology treatment plans. The device lets the user import patient images and data, identify treatment targets and organs at risk, create an optimal treatment plan taking into account patient anatomy, prescribe treatment dose and organ at risk sensitivity, review and approve the plan and then administer the treatment. A scientific basis for the device is the implementation of peer reviewed algorithms of plan parameter optimization and photon and particle dose calculation.

RayStation consists of multiple applications:

- The main RayStation application is used for treatment planning.
- The RayPhysics application is used for commissioning of treatment machines to make them available for treatment planning and used for commissioning of imaging systems.
- The RayTreat application is used for sending plans to treatment delivery devices for treatment and receiving records of performed treatments.

These applications are built on a software platform, containing the radiotherapy domain model and providing GUI, optimization, dose calculation and storage services. The platform uses three Microsoft SQL databases for persistent storage of the patient, machine and clinic settings data.

The RayStation application is divided in modules, which are activated through licensing. A simplified license configuration of RayStation is marketed as RayPlan. RayPlan has a limited set of modules, indicated in the following table.

Planning activity	Module	Available in RayPlan
Automated planning	Plan explorer	No
	Automated breast planning	No
	Fallback planning	No
	Fallback protocol management	No
Patient data management	Patient data management	Yes
Patient modeling	Image registration	Yes
	Structure definition	Yes
	Deformable registration	No
	Eye modeling	No
Plan design	Virtual simulation	Yes
	Plan setup	Yes
	3D-CRT beam design	Yes
	Electron beam design	Yes
	Proton beam design	No
	Brachy planning	Yes
Plan optimization	Plan optimization	Yes
	Multi criteria optimization	No
Plan evaluation	Plan evaluation	Yes
	Robust evaluation	No
	Biological evaluation	No
QA preparation	QA preparation	Yes
Treatment adaptation	Dose tracking	No
	Adaptive replanning	No

In each planning activity the user can perform some operations that are considered to form a basic task or planning activity in oncology. Together, the planning activities cover a complete treatment planning use case. Each planning activity consists of one or more modules; each corresponding to a coherent group of functionalities. A module may include one or several workspaces, where each workspace holds an optimized layout of regions populated with GUI components that are needed to get through the use case of the module.

The device to be marketed, RayStation 12A, contains modified features compared to version RayStation 11B as indicated below:

- Support for eye planning with wedges
    - A wedge can be used to improve the conformity of dose distribution and spare risk organs. The wedge is not patient specific, meaning that the user must choose a wedge from a predefined set of wedges for the treatment machine. Each wedge in the machine model is associated with an identifying name, a physical opening angle, and a material.
- Automatic field in field planning

  - A uniform dose can be achieved on a selected target using automatically generated 3D-CRT fields/segments. Starting from a number of beams (usually 2 or 3) and an initial segment for each beam the action sequentially adds a given number of segments to each beam, choosing apertures and segment weights so that the final dose is approximately uniform on the target. The apertures of the inner segments always have openings that are subsets of the openings of the respective initial segments.
- Brachy therapy support for Elekta Flexitron® afterloaders
  - The connectivity to the Elekta Flexitron® afterloader is validated for the brachy planning in RayStation using the TG43 formalism.
- Electron Monte Carlo dose engine update
  - The previously used plug-in for in-patient transport for the electron Monte Carlo dose engine (VMC++) was replaced by a fully integrated electron Monte Carlo dose engine. In the development of the new dose engine, improvements have been made to increase the accuracy for small cutout sizes.

1.9 Indications for Use

RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

1.10 Technological characteristics summary

The following comparison table summarized the technological characteristics. In the table below, RayStation 12A is compared to the predicate device RayStation 11B.

Item	Compared to RayStation 11B	Comment
Hardware platform	Substantially Equivalent	Both systems use standard office PCs as hardware platform.
Operating system	Substantially Equivalent	Both systems use Windows 10 Professional (or higher) and Windows Server 2012 R2 (or higher).
Target population	Substantially Equivalent	RayStation 11B and RayStation 12A are intended for the same target population and anatomical sites; persons that have been prescribed an external beam radiation therapy or medical oncology treatment.
Anatomical sites	Substantially Equivalent	
Human factors	Substantially Equivalent	In terms of human factors, the systems are considered equivalent. The user interfaces are almost identical.
Standards met	Substantially Equivalent	Both systems comply with the following FDA-recognized consensus standards: IEC 61217:2011, IEC 62083, IEC 62304:2015, IEC 62366-1:2015, ISO 14971:2019 and with IEC 60601-2-68:2014 standard.
Image types	Substantially Equivalent	RayStation 11B and RayStation 12A both support CT, PET and MR images for identifying patient organs and contouring.
Reporting aspects	Substantially Equivalent	When evaluating and approving treatment plans, all necessary data is presented to the user and available in print in both systems.
Image storing	Substantially Equivalent	None of the systems is intended for long term storage of images or other patient data.
Network / remote connections and capabilities	Substantially Equivalent	Both systems are capable of network transfer of patient data using the DICOM protocol. RayStation 12A and RayStation 11B are designed for desktop use and for remote access using standard virtualization techniques. Remote connection to the system is verified in detail and equivalent to local connection.

Cybersecurity	Substantially Equivalent	Both systems are compliant with the requirements listed in the FDA guideline 1825 “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”.

Detailed technology comparison table:

Feature	Description	Present in RayStation 11B (K220141)	Present in RayStation 12A	Significantly changed?
3D visualization	Displays the patient geometry and structures in three dimensions, with the possibility to rotate the patient image. If available, the dose distribution and beam modifiers are shown as well.	Yes	Yes	No
Adaptive replanning	The process of replanning the treatment for a patient, based on information about e.g. patient geometry, biology and dose delivery acquired during treatment.	Yes	Yes	No
Beam commissioning	Modeling of the radiation beam using a limited set of measurements on the clinical beam for commissioning treatment machines to make them available for treatment planning.	Yes	Yes	No
Beam design	Definition of beam orientations, apertures and various beam modifiers in order to manually create a treatment plan.	Yes	Yes	No
Beam set-up	Manual or automatic definition of isocenter, selection of treatment unit from the set of commissioned treatment machines, and specification of gantry/couch/collimator angles.	Yes	Yes	Yes, new functionality Automatic Field in Field planning was added.
Beam’s eye view	Displays the beam’s eye view of the patient structures, fluence and beam modifier settings for any beam.	Yes	Yes	No
Brachy planning	Tools for planning of HDR brachytherapy treatments. Includes channel reconstruction and optimization and editing of dwell times.	Yes	Yes	Yes. Now supports Elekta Flexitron afterloaders.
CyberKnife planning	CyberKnife planning is completely integrated in RayStation. This includes optimization of high quality treatment plans collimated with MLC, fixed cones or iris cones, as well as support for all CyberKnife Synchrony techniques for target tracking and real time motion synchronization.	Yes	Yes	No
Deformable registration	Establishing a point-to-point mapping between two images using a deformation model. Used for mapping of dose and structures between images.	Yes	Yes	No

DICOM RT export	Export of images, structure set, plan, and dose according to the DICOM RT standard.	Yes	Yes	No
DICOM RT import	Import of images, structure set, plan, and dose according to the DICOM RT standard.	Yes	Yes	No
Dose calculation electrons	For electron beams RayStation calculates dose by the Monte Carlo technique. The electron beam phase space is generated in run time by sampling from a phase space model where the electrons are created at the secondary scattering foil. Both the electron transport through the treatment head and the in-patient dose computation is performed using the Monte Carlo algorithm. In versions prior to RayStation 11A, the transport through the treatment head has been handled by a Monte Carlo algorithm developed by RaySearch, while the in-patient transport and dose computation has been the responsibility of the plug-in dose engine VMC++. In RayStation 12A, the VMC++ dose engine has been exchanged with an in-patient Monte Carlo transport and dose scoring algorithm fully developed by RaySearch. Additionally, some minor improvements have been made to the treatment head transport, but this part is essentially the same as in RayStation 11B. There are substantial similarities between the replaced VMC++ code and the EGSnrc code and these two Monte Carlo dose engines agrees on sub-percent level [1][2]. The dose engine developed by RaySearch is similar to the EGSnrc, as has been described in references 11, 12, 17, 24 and 108 in the 008 RSL-D-RS-12A-REF-EN-1.0-2022-06-23 RayStation 12A Reference Manual. Therefore, we conclude that the electron dose engine used in RayStation 12A (fully developed by RaySearch) is substantially equivalent to the electron dose engine used in RayStation 11B (in-patient dose computation handled by VMC++).	Yes	Yes	Yes

	The supporting testing confirms equivalence between the RayStation 11B and RayStation 12A dose engines. Regression tests performed during the electron dose engine validation between the two versions are within tolerance limits which shows a similar level of accuracy between the two dose engines. Acceptance criteria for comparison with previous RayStation dose: The calculated doses shall fail for less than 2% of the data points for gamma 2%/2mm. References: [1] Kawrakow I and Fippel M, "VMC++, a MC algorithm optimized for electron and photon beam dose calculations for RTP," Proceedings of the 22nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society (Cat. No.00CH37143), Chicago, IL, USA, 2000, pp. 1490-1493 vol.2, doi: 10.1109/IEMBS.2000.898024. [2] Kawrakow I, Fippel M, Friedrich K. 3D electron dose calculation using a Voxel based Monte Carlo algorithm (VMC). Med Phys. 1996 Apr;23(4):445-57. doi: 10.1118/1.597673. PMID: 9157256.			
Dose calculation photons	For **photon** beams RayStation calculates dose by the point kernel superposition method (a.k.a. Collapsed Cone) or a Monte Carlo algorithm for radiation transport. The incident energy fluence is modeled as a superposition of a primary energy fluence and a scatter energy fluence. The dose contribution from contamination electrons is calculated by a pencil beam algorithm.	Yes	Yes	No
Dose calculation proton	For **proton** beams RayStation uses either the pencil beam algorithm with the Fermi-Eyges formalism, or a Monte Carlo algorithm for radiation transport. For passive beams the beam model accounts for the collimator and compensator block. For scanning beams the beam model accounts for the spot phase space including effects of air-scatter and beam paths through magnetic deflection elements. The user defined block aperture is taken into account in spot selection and optimization. In addition to this the relative biological effect (RBE) of proton beams is taken into account, resulting in a photon equivalent dose.	Yes	Yes	No

Dose calculation brachy	For brachy plans RayStation calculates dose based on the TG43 formalism.	Yes	Yes	No
Dose display (2D)	Displays the patient geometry with structures superimposed on the image data together with the dose distribution in transversal, sagittal, and coronal directions.	Yes	Yes	No
Dose tracking	Dose tracking scenarios including deformable registration of one CT or CBCT to another and subsequent deformation and accumulation of dose.	Yes	Yes	No
Eye planning	Tools for specifying a highly detailed geometrical model of the eye based on measurements from ultrasound and surgery. Support for positioning of tantalum clips. Import and visualization of fundus images. Creation and dose computation of proton plans with gaze angle-based treatment directions.	Yes	Yes	Yes, Now supports eye planning with wedges.
Fallback planning	Automatic generation of fallback plans using alternative treatment machines and treatment techniques. User-defined protocols specifies the setup of the fallback plans which are automatically generated from the protocols and optimized using dose mimicking functions.	Yes	Yes	No
Image conversion	Conversion of CBCT images to synthetic CT images that can be used for more accurate dose calculations.	Yes	Yes	No
Inverse planning	The user can define optimization settings such as optimization tolerance and maximum number of iterations as well as segmentation settings on the multileaf collimator and the Pencil Beam Scanning spot pattern. An interface for controlling the optimization process is provided and the progress of optimization is displayed in a view. The system generates control points for step-and shoot MLC plans, Sliding Window plans (DMLC), rotational plans (VMAT), 3DCRT plans, Wave Arc plans, TomoTherapy plans and proton Pencil Beam Scanning plans, using the defined optimization problem. The inverse planning can be carried out either through a conventional inverse approach or by using multi-criteria optimization (photons and protons only).	Yes	Yes	No

LET evaluation	Computation and evaluation of dose-averaged LET (Linear Energy Transfer) for proton plans. LET is an additional physical quantity that can be used to assess the radiobiological effect of the proton radiation.	Yes	Yes	No
Machine database	Microsoft SQL database for storage of beam model parameters, machine constraints and dose curves with dosimetric data for treatment units.	Yes	Yes	No
MR based planning	Allowing MR-images as planning images and base dose computation on material override ROIs.	Yes	Yes	No
Optimization functions	The optimization functions are specified in terms of objectives and constraints to form the optimization problem that is solved by the optimization engine.	Yes	Yes	No
Patient anatomy modeling	Manual and semi-automatic segmentation tools for contouring ROIs slice by slice together with semi-automated generation of the patient outline ROI. The model-based segmentation technique allows for semi-automatic delineation of structures by matching 3D shape models of the structures to new image data. With atlas-based segmentation, the user can define templates consisting of already segmented image data and use this template for segmentation of new patient images. With deep learning segmentation, the user can use trained deep learning models for automatic segmentation of new patient images. (The model training is performed offline on clinical CT and structure data.)	Yes	Yes	No
Patient database	Microsoft SQL database for storage of all patient and plan data. Not for long term storage.	Yes	Yes	No
Plan Explorer	The system computes a large set of plans according to given rules and the user is provided with tools to select good plans from these.	Yes	Yes	No
Quality assurance preparation	Tools for transferring the clinical plan to a phantom and recalculate dose. The output is the dose distribution in DICOM format or a 2D dose plane and a QA report. Predicted EPID response is retrieved by photon dose computation in a specially designed phantom.	Yes	Yes	No

RBE dose handling	RBE (Relative Biological Effectiveness) models can be defined and commissioned. For proton treatments, the user can select whether to look at RBE-corrected dose or physical dose. Dose summation is only possible for photon doses and RBE-corrected proton doses.	Yes	Yes	No
Robust evaluation	Tools used to answer questions of how the dose distribution would appear if the patient setup at the time of treatment does not fully correspond to the planning CT. A model of patient uncertainties such as CT inaccuracy and setup errors is used to compute a set of scenario doses for evaluation.	Yes	Yes	No
Robust optimization	Optimization where a model of patient uncertainties such as CT inaccuracy, setup errors or organ motion is used during the optimization.	Yes	Yes	No
Scripting	Scripting gives programmatic access to functionality, excluding user risk mitigations. Through scripting, the clinic specific procedures can be automated. The operating system and other applications can be accessed.	Yes	Yes	No
Supported treatment positions	HFS, FFS, HFP, FFP	Yes	Yes	No
	Decubitus left/right	Yes	Yes	No
	Seated position (for ions)	Yes	Yes	No
System integrity tools	Hardware based license, preventing unauthorized useable copies to be made. Checksum control of binary files to prevent tampering. Data in the patient and machine databases only available for users with administrator rights.	Yes	Yes	No
TomoTherapy planning	Planning for TomoTherapy machines is completely integrated in RayStation. Also provides tools for selection of targets and imaging angles for the TomoTherapy machine to use for target tracking during delivery.	Yes	Yes	No
Treatment adaptation	A general concept where the treatment plan is adapted during the course of treatment. Tools available today include deformable dose accumulation, CBCT dose calculation and replanning scenarios.	Yes	Yes	No
Treatment plan approval	Approval of the preferred treatment plan and referenced ROIs by authorized medical staff. Once a treatment plan is approved, it is locked for any further modification.	Yes	Yes	No

Treatment plan creation	Treatment plan creation with specification of plan properties such as number of fractions and delivery technique.	Yes	Yes	No
Treatment plan evaluation	Evaluation of a single plan. Comparison of dose distributions and DVH curves of two or three plans.	Yes	Yes	No
Treatment delivery	An approved plan can be assigned to fractions in a treatment course and sent to the treatment delivery device. RayTreat offer treatment room interfaces for patient positioning, imaging and plan delivery.	Yes	Yes	No
Undo/redo and auto recovery	The undo stack is saved to the database, enabling recovery of RayStation after crash. The user may redo all or selected changes at reopen of patient after crash.	Yes	Yes	No
Virtual Simulation	Setup of isocenter, beam arrangements and basic aperture design. Export to laser systems for patient marking.	Yes	Yes	No

1.11 Assessment of non-clinical performance data

Software verification and validation testing were conducted, and documentation was provided 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, since a failure or latent flaw in the software could directly result in serious injury or death to the patient.

Support for eye planning with wedges – Validation of the eye planning feature extended to include wedges was performed as part of the dose engine validation for proton ocular treatments. The test cases cover line doses in homogeneous phantoms using a square aperture and a wedge mounted with varying opening angles and positions. Depth dose curves with ranges and modulations are used in the validation. An interval is used for the opening angle of the wedge and for the lateral position of the opening edge of the wedge with respect to the central axis. Depth-dose profiles along the central axis were acquired with a plane-parallel chamber in a water tank. The accuracy requirements are related to:

- The SOBP distal fall-off of the central axis depth dose curve
- 95% and 98% of the computed depth dose values with Gamma pass rates

The requirements are met by the data in the validation report. The proton dose computation for proton ocular treatments in RayStation 12A has been successfully validated for accuracy in clinically relevant settings according to specification.

Automatic field in field planning - Validation of the new feature for creating field in field plans for e.g. 3DCRT plans with multiple segments in each beam was performed as part of the overall system validation.

The requirements are that

- For a 3D-CRT plan, the merged beams’ MU shall agree with original beams’ MU.
- Merged beams’ segments shall keep original shapes.
- MU and segment weights after split are subdivided correctly and that split beams are managed correctly in terms of ordering and ROI handling.

Testing shows that the segment MUs and shapes agree, beam and segment administration and handling are correct and that all beams created by the split beam action have the same Treat and Protect ROIs as the beam that was split. These tests demonstrate that RayStation 12A can safely perform field in field planning.

Brachy Therapy now support Elekta Flexitron® afterloaders – Validation of the HDR brachytherapy planning for Elekta Flexitron afterloaders was performed as part of the Dose Engine validation of Brachy TG43.

Computed doses have been compared with reference doses, i.e. from published consensus data sets, from measurements or from independent and well-established systems for dose computation. The reference doses consist of point doses, line doses, as well as 2D and 3D doses. The reference dose sources are

- Published consensus data
- Measured doses
- Doses computed in two major competing TPS
- Doses computed with an independent Monte Carlo software

RayStation provides support for TG43 dose computation with user specified TG43 parameters for any applicable source. Comparison to QA along-away data ensures that the dose engine can accurately reproduce the dose for a variety of sources given that the input data is correct. Measurement from EQUAL-ESTRO relates computed dose to delivered dose for a setup with three dwell positions. Comparison to an independent and TG43 compliant treatment planning system is used to further validate the correct superposition of dose from a large number of dwell positions. Finally, the comparison to an independent Monte Carlo system decouples the dependence to the TG43 formalism and provides a fully independent validation of a complete treatment plan. The validation demonstrates that the dose computation is adequate for clinical use.

Electron Monte Carlo dose engine update – The electron dose calculation in RayStation supports LINACs using the dual foil scattering technique with applicators and cutouts. The dual foil assembly shapes the electron beam phase space in the upper part of the treatment head (i.e. towards the vacuum window). The applicator and cutout further shape the beam to yield clinically usable lateral flatness and penumbras while minimizing radiation leakage outside of the field.

The electron phase space model in RayStation is designed to model the arrangement sketched above. The implementation is parameter driven and thus generic with respect to a typical dual foil, applicator and cutout arrangement.

The validation strategy is to compare doses computed with RayStation 12A to reference doses. The different reference doses used are

- Measured doses.
- Doses computed in a well-established competing TPS.
- Doses computed with earlier versions of RayStation.
- Doses computed in BEAMnrc/egs++.

Two different gamma criteria for comparison with another TPS or measurement are evaluated for each test case, with specified requirements on level of agreement.

The fraction of the calculated dose data points for comparison with previous RayStation dose that fail has been evaluated, and the fraction of the calculated dose data points for comparison to BEAMnrc/egs++ that fail has been evaluated.

Validation of the new dose engine has been performed which demonstrates that the dose computation is adequate for clinical use.

1.11.1 Conclusion

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the RayStation 12A device should perform as intended in the specified use conditions, and the performance testing demonstrates that the RayStation 12A device performs comparably to the predicate device that is currently marketed for the same intended use.