

December 18, 2025

RefleXion Medical, Inc.
Leena Kadakia
Vice President, Regulatory Affairs
25881 Industrial Blvd. Suite 275
Hayward, California 94545

Re: K252071

Trade/Device Name: RefleXion Medical Radiotherapy System, Reflexion X2
Regulation Number: 21 CFR 892.5060
Regulation Name: Fludeoxyglucose F18-Guided Radiation Therapy System
Regulatory Class: Class II
Product Code: QVA, IYE, MUJ
Dated: July 1, 2025
Received: November 19, 2025

Dear Leena Kadakia:

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,

A handwritten signature in black ink that reads "Lora Weidner". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

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

Indications for Use

510(k) Number (if known)
K252071

Device Name
RefleXion Medical Radiotherapy System, Reflexion X2

Indications for Use (Describe)

The RefleXion Medical Radiotherapy System is indicated for treatment planning and precise delivery of image-guided radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery for tumors or other targeted tissues anywhere in the body when radiation treatment is indicated while minimizing the delivery of radiation to vital healthy tissue. The megavoltage X-ray radiation is delivered in a rotational, modulated, image-guided format in accordance with the physician-approved plan.

The RefleXion Medical Radiotherapy System is also indicated for FDG-guided treatment which includes modeling, planning and precise delivery of FDG-guided radiation therapy, a type of Biology-guided Radiotherapy (BgRT), in five or fewer fractions for adults. It is indicated for tumor volumes in lung and bone subject to potential motion and positional uncertainty that have each been assessed with on-board PET/CT prior to delivery for adequate localization, sufficient FDG metabolic activity, local contrast and consistent biodistribution to meet the RMRS requirements, while minimizing the delivery of radiation to vital healthy tissue. BgRT involves the detection of signals from F18 during active beam delivery as a guide to deliver megavoltage X-ray radiotherapy in a rotational, modulated format in accordance with a physician approved treatment plan.

For complete fludeoxyglucose F18 prescribing information, refer both to the current medical imaging agent labeling and to this device labeling under "FDG Medical Imaging Agent Information".

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.

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	510(k) SUMMARY	Traditional 510(k) RMRS, RefleXion X2
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This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information

Submitter Name: RefleXion Medical Inc.
Address: 25881 Industrial Boulevard, Hayward, California 94545

Primary Contact:

Contact Person: Leena Kadakia
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Date Prepared: December 16, 2025

Device Name

Trade Name: RefleXion Medical Radiotherapy System (RMRS)
Device Name: RefleXion X2
Common Name: Fludeoxyglucose F18-Guided Radiation Therapy System
Classification Name: Radiology
Regulation Number: 21 CFR 892.5060
Regulatory Class: Class II
Primary Product Code: QVA
Secondary Product code: IYE, MUJ
Panel: Radiology

Predicate Device

Predicate Device Name: RefleXion Medical Radiotherapy System (RMRS)
510(k) Number: DEN220014
Manufacturer: RefleXion Medical, Inc.
Reference Submission (if applicable): DEN220014

Device Description

The RefleXion X2 System is a hybrid imaging and treatment platform designed to deliver multiple forms of external beam radiation therapy, including Intensity-Modulated Radiation Therapy (IMRT), Stereotactic Body Radiation therapy (SBRT), Stereotactic Radiotherapy (SRT), Stereotactic Radiosurgery (SRS), and biology-guided radiotherapy (BgRT).

The subject device (X2 System) is based on the same fundamental design as the X1 System (predicate device, DEN220014). Both systems integrate radiation delivery, imaging (CT and PET), and treatment planning capabilities into a single device.

- 6 MV photon radiotherapy delivery
- Positron Emission Tomography (PET) imaging
- Kilovoltage (kV) X-ray CT imaging
- Treatment planning

The radiation delivery subsystem includes a LINAC mounted within the therapy plane, utilizing a fixed primary collimator, adjustable upper and lower jaws, and a multileaf collimator (MLC) to shape and modulate the treatment beam. PET detector arcs are also mounted within the therapy plane to detect emissions from radiotracers during treatment, enabling biology-guided radiotherapy (BgRT). The kVCT imaging subsystem operates in a separate imaging plane and provides anatomical imaging for patient setup and verification prior to treatment delivery.

The X2 System incorporates several design updates relative to the X1 System, including enhancements to the PET subsystem, updates to kVCT components, hardware improvements aimed at manufacturing reliability and serviceability, software infrastructure upgrades, usability enhancements such as intra-fraction PET image viewing and multi-target treatment workflows, and cybersecurity improvements. These changes do not alter the device's intended use, fundamental scientific technology, or safety and effectiveness.

No new patient-contacting materials, contamination pathways, or reprocessing requirements have been introduced. Consequently, the risk profile of the device, including the risk of infection or other adverse events, remains unchanged from the predicate device.

Comparison of Technological Characteristics with the Predicate Device

The RefleXion X2 System shares the same fundamental scientific technology and intended use as the predicate RefleXion X1 System (DEN220014), including the integration of PET imaging with radiation therapy delivery for the treatment of cancer. Both systems use image-guided radiotherapy (IGRT) and biology-guided radiotherapy (BgRT) within the same clinical and environmental operating conditions.

The X2 System includes several technological enhancements compared to the predicate device, including an expanded PET subsystem that increases the axial field of view from 5.3 cm to 21.5 cm through the use of four detector rows instead of one, and the integration of onboard GPUs for improved image processing. The kVCT subsystem has also been updated with a new X-ray tube and high voltage

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generator to enhance imaging performance and reliability. Additional changes include minor hardware updates for manufacturability and serviceability, usability improvements such as an intra-fraction PET image viewer and workflow tools for multi-target treatment, and software updates including a transition to a Linux-based operating system with improved cybersecurity controls. These modifications do not alter the core radiation delivery technology, intended use, or safety profile of the device. Therefore, the RefleXion X2 System is considered substantially equivalent to the RefleXion X1 System.

Intended use

The RefleXion X2 is a radiation therapy system that offers conventional CT-guided treatments and F18-guided treatments. It combines the functionality of a positron emission computed tomography detection system and a linear accelerator to acquire images of positron-emitting F18 for the purpose of guiding the delivery of megavoltage X-rays for oncologic treatment with radiation therapy.

Indications for Use

The RefleXion Medical Radiotherapy System is indicated for treatment planning and precise delivery of image-guided radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery for tumors or other targeted tissues anywhere in the body when radiation treatment is indicated while minimizing the delivery of radiation to vital healthy tissue. The megavoltage X-ray radiation is delivered in a rotational, modulated, image-guided format in accordance with the physician-approved plan.

The RefleXion Medical Radiotherapy System is also indicated for FDG-guided treatment which includes modeling, planning and precise delivery of FDG-guided radiation therapy, a type of Biology-guided Radiotherapy (BgRT), in five or fewer fractions for adults. It is indicated for tumor volumes in lung and bone subject to potential motion and positional uncertainty that have each been assessed with on-board PET/CT prior to delivery for adequate localization, sufficient FDG metabolic activity, local contrast and consistent biodistribution to meet the RMRS requirements, while minimizing the delivery of radiation to vital healthy tissue. BgRT involves the detection of signals from F18 during active beam delivery as a guide to deliver megavoltage X-ray radiotherapy in a rotational, modulated format in accordance with a physician approved treatment plan.

For complete fludeoxyglucose F18 prescribing information, refer both to the current medical imaging agent labeling and to this device labeling under "FDG Medical Imaging Agent Information".

Table 1 - Comparison of the modified device and predicate device (updated characteristics)		
Device Characteristic	Predicate Device: RefleXion X1, DEN220014	Modified Device: RefleXion X2
PET system		
Axial FOV (cm)	5.3	21.5
Detector Rows	1	4

	510(k) SUMMARY	Traditional 510(k) RMRS, Reflexion X2
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Table 1 - Comparison of the modified device and predicate device (updated characteristics)

Device Characteristic	Predicate Device: Reflexion X1, DEN220014	Modified Device: Reflexion X2
Detector Elements	12	48
Energy resolution	< 15%	< 20%
PET Ring Diameter (cm)	106.1	91.3
GPU(s)	None	On gantry
Sensitivity @ 0cm	> 0.1 cps/kBq	> 2 cps/kBq
Scatter fraction	<45%	<48%
Spatial Resolution	Transverse/Axial values are combined for subject device. Trans/axial @ 1 cm < 5.5 mm Trans/axial @ 10 cm < 6.0 mm	Transverse/Axial values are combined for subject device. Trans/axial @ 1 cm < 5.6 mm Trans/axial @ 10 cm < 7.7 mm
Timing Resolution (ps)	≤ 1000 ps	≤ 500 ps
Number of imaging planes (aka, slices)	19	95
kVCT System		
Tube/Generator	48kW	Updated design, same power used
Usability enhancements		
Image registration tools	kVCT/kVCT image overlay with adjustable checkerboard and opacity blending tools; manual registration using bone or soft tissue; translations and pitch/roll/yaw determination	kVCT/kVCT image overlay with adjustable checkerboard and opacity blending tools; manual registration using bone or soft tissue; translations and pitch/roll/yaw determination. Added support for auto-calculation of registration of kVCT and simulation CT for patient localization during delivery (automatic rigid registration)
Multiple Target workflow	Manual only	Manual and optional integrated workflow for Multiple Targets (1 BgRT + 1 IGRT, or multiple IGRT targets)
PET intra-fraction image viewer	Not available	Available
Nominal Dose Rate	850 cGy/min	1000 cGy/min

Performance Data (Non-Clinical Testing)

Bench performance testing for the X2 System was completed using equivalent test methods as the X1 System and ensures adherence to the special controls outlined in 21 CFR 892.5060.

Verification testing was performed for the PET subsystem to assess the following:

- PET NEMU NU-2 performance tests for spatial resolution, scatter fraction and count rate measurements, sensitivity, and image quality
- PET System Performance Checks
- PET image reconstruction and attenuation correction

All tests passed the pre-defined acceptance criteria.

Verification testing was performed to assess the performance and integration of the following subsystems:

- kVCT
- MV x-ray detectors (MVD)
- Beam generation
- Collimation
- Couch
- Treatment planning
- Treatment delivery

SCINTIX Performance Testing

To support compliance with special controls 4 (iii) and 4 (iv) per 21 CFR 892.5060, an extensive set of bench phantom tests was conducted to evaluate the dosimetric accuracy of SCINTIX treatment delivery. Treatment plans were generated from CT and PET scans of the experimental setup followed by the treatment delivery workflow with FDG injected targets (both moving and stationary), nearby “organ at risk” (OAR) structures and background materials. Two types of phantoms were used:

1. Large Anthropomorphic Phantom (LAP) with independently moving targets and OARs
2. ArcCHECK with custom FDG fillable inserts

The dose delivery accuracy was measured using industry standard radiochromic film, ion chambers, the ArcCHECK phantom and post-delivery analysis of the actual machine instructions. Depending on the test conditions, one or more of the following acceptance criteria were used:

Dosimetric Criteria:

- Gamma Index - The acceptance criteria required that 90% of the comparison points (that were above 10% of the prescription dose) were within either 3% in dose or closer than 3mm in 3D space (DTA or distance to agreement) to a point with the same dose.

- Dosimetric Coverage – Dose at all points measured on film within the CTV was $\geq 97\%$ of prescription dose, but $\leq 130\%$ of maximum planned dose.
- OAR Dose - For nearby OARs, the maximum dose was measured using radiochromic film over all valid dose points and the acceptance criteria was that the dose measured on the film must be a value that is $\leq 3\%$ higher than the bDVH maximum dose for that OAR as calculated by the plan.
- Margin Loss - This is the maximum distance (measured in any plane) from the PTV contour to the 97% prescription isodose contour measured in the reference frame of the moving target.

The performance of the PET evaluation step was also evaluated.

The following scenarios were covered with the results indicating which dosimetric criteria were used:

Test (s) & Objective Description	Results
To demonstrate the SCINTIX dose delivery accuracy for: Moving target with 3-D respiratory and 3-D non-respiratory motion; OAR independent motion	Both dosimetric coverage and margin loss criteria as well as OAR dose criteria were met.
To demonstrate the SCINTIX dose delivery accuracy to target(s) and measure dose to OARs: <ul style="list-style-type: none"> • single step shift motion • 3D step shift (3 mm in x,y, and z directions) 	Both dosimetric coverage and margin loss criteria as well as OAR dose criteria were met.
To demonstrate the SCINTIX dose delivery accuracy for various clinical situations of targets: <ul style="list-style-type: none"> • increase or decrease in contrast between target and background from planning to delivery; • biodistribution changes in the target; • type of background around the target; • partially avid PET target • special edge cases (stationary) to demonstrate robustness of the SCINTIX technology under challenging situations 	<p>Gamma index met the dose accuracy criteria in most cases except as noted below.</p> <p>The PET evaluation did not pass and prevented delivery for cases where there was a significant change in biodistribution in the target, change in biodistribution between planning and delivery, low contrast between the target and background, a situation when an FDG-avid target moves into the BTZ, or a change in the background signal.</p> <p>In cases with significant anisotropic biodistribution changes resulting in a change in peak PET activity location relative to the target, the dose shifted relative to the target, and the dose accuracy criteria were not met. Image review during PET evaluation per the Treatment Delivery</p>

Test (s) & Objective Description	Results
	Manual is required and re-planning is recommended in these cases.
Test of BTZ monitor interlock to ensure treatment is halted with large motion changes (target moves outside BTZ; OAR moves into BTZ)	The BTZ monitor performed as expected, stopping the treatment if the target moved outside the BTZ or a PET-avid OAR moved into the BTZ during delivery.
Testing with non-periodic tracking mode to demonstrate the SCINTIX dose delivery accuracy for various clinical situations where the target is stationary or subject to sudden shifts.	For all tests with stationary targets gamma index criterion was met. For cases with sudden target shifts, dosimetric coverage and margin loss criteria were met.
Testing with periodic tracking mode to demonstrate the SCINTIX dose delivery accuracy to target(s) with respiratory motion patterns for various clinical situations.	Both dosimetric coverage and margin loss criteria as well as OAR dose criteria were met.
Tests evaluating special edge cases (moving targets with low contrast; changes in motion pattern between planning and delivery; variations in tracking mode parameter choices)	For all tests with stationary targets gamma index criterion was met. For all tests with moving targets both dosimetric coverage and margin loss criteria as well as OAR dose criteria were met.
Multi-target testing for integrated workflow (combination of one SCINTIX and IGRT targets; out-of-session resumptions to MTT deliveries)	Both dosimetric coverage and margin loss criteria as well as OAR dose criteria were met.

The results of the BgRT dosimetry testing provided objective evidence that the X2 System can deliver BgRT treatments with the required dosimetric accuracy under a variety of target and environment conditions including certain edges cases.

PET Intrafraction Image Validation:

Intrafraction PET images during SCINTIX delivery are intended to visualize the average position of the target or any nearby hot (i.e., FDG-avid) OARs after each couch pass. These images help the user to consider the need for re-localization or treatment termination prior to encountering a BTZ monitor interlock.

Validation testing demonstrated that intended users can successfully interpret intrafraction PET images during real-time treatment to determine the appropriate user actions for three different clinical scenarios during a treatment fraction based on the image review criteria (alignment of the PET signal with the appropriate contours and nearby PET avid OARs):

- Continue treatment without re-localization
- Continue treatment with re-localization
- Terminate treatment

Additional bench performance testing included:

- Safety/Interlock tests to ensure risk mitigations performed as specified.
- Validation testing, including end-to-end tests, and tests to ensure the system performance checks function as intended.

Usability/Human Factors:

Usability testing of the RefleXion X2 System was conducted following FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff” (Feb 2016) and IEC 62366-1:2015 +A1:2020. The testing was performed to measure the usability of the RefleXion X2 System treatment planning system, treatment delivery system and medical physics workspace with representative users. The testing also demonstrated the safety and effectiveness of the controls implemented for use-related hazards.

Table 2 summarizes the Usability participant demographics:

Table 2: Summary of Participant Demographics					
	Radiation Oncologists N=7	Dosimetrists N=3	Medical Physicists N=17	Nuclear Med Techs N=1	Radiation Therapists N=15
Years of Experience – average (range)	8.71 (1 – 20)	12.0 (7 – 19)	13.94 (3 – 33)	15.0 (15)	16.13 (6 – 36)
Institution type: (Academic/Community/Private)	4/3/0	3/0/0	12/4/1	0/0/1	8/5/2
Experience with RefleXion X1 (Yes/No)	4/3	3/0	4/11	1/0	4/13

Critical tasks were identified and tested in a simulated use environment that included both normal operations and imposed scenarios. Testing included new usability features (kVCT image registration, PET intrafraction image viewer, and multi-target workflow tools). Two primary measurements were collected to assess the safety of the RefleXion X2 System: task performance data collected by study observers and participant safety-related feedback. Results of the testing confirmed the execution of all critical tasks were found to be safe and effective for the intended users, its intended uses and the use environment.

Clinical Performance Data

No new clinical testing was conducted for the RefleXion X2 System. The applicable special control requires demonstration that the system performs as intended under anticipated conditions of use, including adequate image quality for clinical interpretation, consistent performance across treatment fractions, sufficient system sensitivity, appropriate administered radiopharmaceutical dose, and evaluation of adverse events.

New clinical testing was not necessary because the RefleXion X2 System has the same intended use and similar technological characteristics as the predicate RefleXion X1 System and does not introduce changes to previously available images that affect imaging performance or clinical use. Clinical performance data previously submitted for the predicate device (DEN220014), together with non-clinical bench testing, validation, and labeling review, are sufficient to demonstrate compliance with the applicable special controls and to support a determination of substantial equivalence.

Software

The RefleXion X2 System software documentation and testing provided demonstrates that the device meets all requirements outlined in the FDA guidance document “Guidance of Premarket Submissions for Device Software Functions” for Enhanced documentation level.

Electromagnetic Compatibility and Electrical Safety

Electrical safety and electromagnetic compatibility testing were performed by a third-party accredited lab per the following standards, and the results were found to be acceptable. These are the same standards from the predicate device, updated to currently recognized versions.

Standard Number	Edition	Title
ANSI/AAMI ES 60601-1	2005, AMD1:2012, AMD2:2020	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
ISO 14971	2019	Medical devices – Application of risk management to medical devices
IEC 62304	2006 + AMD1:2015	Medical device software –Software life cycle processes
IEC 60601-1-2	2014 +AMD1:2020	Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-3	2008, AMD1:2013, AMD2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

Standard Number	Edition	Title
IEC 60601-1-6	2010, AMD1:2013, AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1	2015 + AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-2-1	2020	Medical electrical equipment Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
IEC 60601-2-44	2009, AMD1:2012, AMD2:2016	Medical electrical equipment - Part 2-44: Requirements for the basic safety and essential performance of x-ray equipment for computed tomography
IEC 60601-2-68	2014 (First Edition)	Medical electrical equipment – Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

Testing was performed in accordance with the following standards and found to be acceptable:

Standard Number	Edition	Title
UL 62368-1	2014	Audio/Video, Information And Communication Technology Equipment - Part 1: Safety Requirements
IEC 60976	2007	Medical electrical equipment – Medical electron accelerators – Functional performance characteristics
IEC 61217	2011	Radiotherapy Equipment – Coordinates, movements and scales
IEC 62083	2009	Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
NEMA NU-2	2018	Performance Measurements of Positron Emission Tomographs

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Substantial Equivalence Conclusion

The Reflexion X2 System shares the same intended use, indications for use, technological characteristics, overall clinical workflow, and principles of operation as the predicate device, the Reflexion X1 System. The subject device has the same intended use and similar technological characteristics as the predicate device. Differences do not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.