June 18, 2026

InformAI, Inc.
Jackie Coleman
Regulatory Lead
2450 Holcombe Blvd.
Houston, Texas 77021

Re: K253050
Trade/Device Name: RadOncAI
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: May 19, 2026
Received: May 19, 2026

Dear Jackie Coleman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiologic 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.

510(k) Number *(if known)*
K253050

Device Name
RadOncAI

Indications for Use *(Describe)*
RadOncAI is indicated for use in a clinical setting by radiation oncologists, medical physicists, and dosimetrists to configure and review radiotherapy treatment plans for adult patients with malignant or benign head-and-neck disease.

The software accepts:
CT-simulation scan
Clinician-defined planning target volumes; and
Clinician-supplied data of organs-at-risk (OARs)

Using these inputs, RadOncAI generates a patient-specific preliminary dose distribution that includes:
Estimated achievable dose coverage to the planning target volume(s); and
Estimated achievable sparing of surrounding OARs.

The directive derived from the AI-generated plan must be reviewed, revised and approved by a qualified professional before clinical implementation. The AI-generated dose distribution generated by the software is intended to be transferred to a compatible radiotherapy TPS or reviewed using DICOM-RT compliant software prior to further use in clinical workflows. RadOncAI is not intended for primary diagnosis, autonomous clinical decision-making, delivery of radiation, or use in patient populations, anatomic sites, or treatment modalities outside the indications stated above. Caution: Federal law restricts this device to sale by or on the order of a physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

InformAI, Inc.

This 510(k) Summary is in conformance with 21 CFR 807.92

Submitter: InformAI, Inc.
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Houston, Texas 77021
United States

Primary Contact: Jim Havelka, CEO
InformAI, Inc.
Email: jcoleman@informai.com
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Device Name and Classification

Trade Name: RadOncAI
Common Name: Radiation Treatment Planning Support Software; AI-Powered Dose Prediction Software
Classification: Class II
Regulation Number: 21 CFR § 892.5050 Medical charged-particle radiation therapy system
Classification Panel: Radiology
Product Code: MUJ

Predicate Device:

	Predicate Device
Trade Name	Oncospace
Common Name	Oncospace
510(k) Submitter / Holder	Sigrid Schoepel Oncospace, Inc.
510(k) Number	K222803
Classification	Class II
Regulation Number	21 CFR § 892.5050 Medical charged-particle radiation therapy system
Classification Panel	Radiology
Product Code	MUJ

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

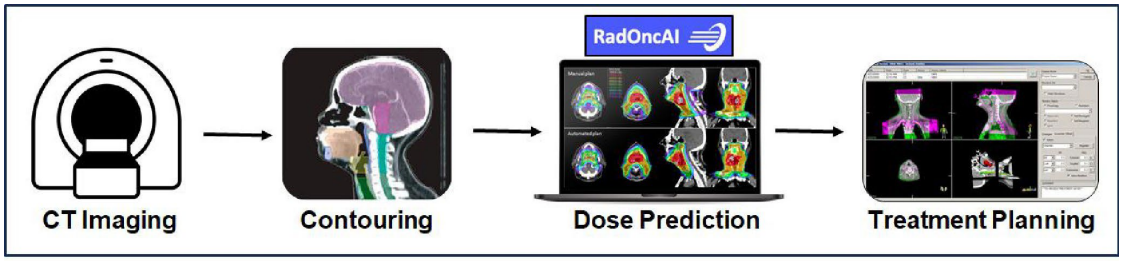
Device Description

RadOncAI is a software-only Class II medical device; it is an artificial intelligence-guided (AI/ML) dose prediction platform for head and neck radiation therapy treatment planning. The device enables clinicians to generate high-quality, patient-specific dose plans. The software takes the patient's diagnostic CT images and clinician-defined targets/organs-at-risk as inputs, and produces a predicted, optimized 3D radiation dose distribution as the output. The device employs locked machine learning models that are not modifiable by the end user. RadOncAI works in conjunction with, and does not replace, a treatment planning system (TPS). The device does not perform final dose calculation for treatment delivery. Rather, the generated preliminary dose predictions must be transferred to a compatible Treatment Planning

System (TPS), and reviewed by qualified radiation therapy professionals, who optimize and finalize the dose treatment plan prior to clinical implementation.

RadOncAI is a locked supervised machine-learning device. Model training, internal validation/tuning, and development testing were completed before final FDA validation. The final FDA validation cohort was assembled separately and was used only to evaluate the locked model. Prior to selection of the final FDA validation cohort, anonymized patient identifiers associated with the model training/development datasets were identified and excluded from the regulatory validation candidate pool. The final 500-patient FDA validation cohort, including the 50-case clinical QC subset, was therefore patient-level distinct from the model training/development datasets. Training data comprised historical adult head and neck radiotherapy cases with available treatment-planning image/structure information, clinician-defined targets and OARs, prescription information, and clinically delivered or clinically accepted photon treatment-planning dose data appropriate for model development. Data exclusions included: cases outside the adult head and neck intended-use population; cases lacking required imaging, structure, prescription, or dose data; cases not meeting clinical planning-quality requirements for model-development use.

The radiation oncology workflow with RadOncAI is shown below:



Intended Use

RadOncAI is indicated for use in a clinical setting by radiation oncologists, medical physicists, and dosimetrists to configure and review radiotherapy treatment plans for adult patients with malignant or benign head-and-neck disease. The AI-generated dose distribution is exported as a DICOM RT Dose object and is intended to be transferred to a compatible radiotherapy TPS or reviewed using DICOM-RT compliant software prior to further use in clinical workflows. This device is for prescription use by order of a clinician.

Indications for Use

RadOncAI is indicated for use in a clinical setting by radiation oncologists, medical physicists, and dosimetrists to configure and review radiotherapy treatment plans for adult patients with malignant or benign head-and-neck disease.

The software accepts:

- CT-simulation scan
- Clinician-defined planning target volumes; and
- Clinician-supplied data of organs-at-risk (OARs)

Using these inputs, RadOncAI generates a patient-specific preliminary dose distribution that includes:

- Estimated achievable dose coverage to the planning target volume(s); and
- Estimated achievable sparing of surrounding OARs.

The directive derived from the AI-generated plan must be reviewed, revised and approved by a qualified professional before clinical implementation. The AI-generated dose distribution generated by the software is intended to be transferred to a compatible radiotherapy TPS or reviewed using DICOM-RT compliant software prior to further use in clinical workflows. RadOncAI is not intended for primary diagnosis, autonomous clinical decision-making, delivery of radiation, or use in patient populations, anatomic sites, or treatment modalities outside the indications stated above. ***Caution: Federal law restricts this device to sale by or on the order of a physician.***

Comparison of Technology Table

The table below provides a detailed comparison of technology:

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Product Code	MUJ (21 CFR 892.5050)	MUJ (21 CFR 892.5050)	Same. Both devices are classified under the same product code for radiation therapy treatment planning systems.
Device Classification	System, Planning, Radiation Therapy Treatment (Class II)	System, Planning, Radiation Therapy Treatment (Class II)	Same. Both devices share the same classification name and regulatory class.
Intended Use	RadOncAI is indicated for use in a clinical setting by radiation oncologists, medical physicists, and dosimetrists to configure and review radiotherapy treatment plans for adult patients with malignant or benign head-and-neck disease. The AI-generated dose distribution is exported as a DICOM RT Dose object and is intended to be transferred to a compatible radiotherapy TPS or reviewed using DICOM-RT compliant software prior to further use in clinical workflows. This device is for	Oncospace is used to configure and review radiotherapy treatment plans for a patient with malignant or benign disease in the prostate, head, and neck regions. It allows for set up of radiotherapy treatment protocols, association of a potential treatment plan with the protocol(s), submission of a dose prescription and achievable dosimetric goals to a treatment planning system, and review of the treatment plan. It is intended for use by qualified, trained radiation therapy professionals. This device is for prescription	Substantially Equivalent. Both devices provide AI-generated dosimetric guidance for external beam radiotherapy treatment planning for head and neck cancer, intended for use by qualified radiation therapy professionals. Both require output to be reviewed in a TPS before clinical use. The subject device is indicated for head and neck only; the predicate also covers prostate cancer. The narrower anatomical scope does not raise new questions of safety or effectiveness.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
	prescription use by order of a clinician.	use by order of a physician.	
Indications for Use	RadOncAI is indicated for use in a clinical setting by radiation oncologists, medical physicists, and dosimetrists to configure and review radiotherapy treatment plans for adult patients with malignant or benign head-and-neck disease. The software accepts: 1) CT-simulation scan, 2) Clinician-defined planning target volumes; and 3) Clinician-supplied data of organs-at-risk (OARs). Using these inputs, RadOncAI generates a patient-specific preliminary dose distribution that includes: Estimated achievable dose coverage to the planning target volume(s); and Estimated achievable sparing of surrounding OARs. The directive derived from the AI-generated plan must be reviewed, revised and approved by a qualified professional before clinical implementation. The AI-generated dose distribution generated by the software is intended to be transferred to a compatible radiotherapy TPS or reviewed using DICOM-RT compliant software prior to further use in clinical workflows. RadOncAI is not intended for primary diagnosis, autonomous clinical decision-making, delivery of radiation, or use in	Oncospace is used to configure and review radiotherapy treatment plans for a patient with malignant or benign disease in the prostate, head, and neck regions. It allows for set up of radiotherapy treatment protocols, association of a potential treatment plan with the protocol(s), submission of a dose prescription and achievable dosimetric goals to a treatment planning system, and review of the treatment plan. It is intended for use by qualified, trained radiation therapy professionals (such as medical physicists, oncologists, and dosimetrists). This device is for prescription use by order of a physician.	Different. The differences do not constitute a new intended use. Both devices are prescription-use radiation treatment planning support software tools used by qualified radiation therapy professionals to configure and review radiotherapy treatment plans in conjunction with a treatment planning system. RadOncAI is limited to adult patients with malignant or benign head-and-neck disease, while the predicate includes patients with malignant or benign disease in the prostate, head, and neck regions; this narrower anatomical scope does not raise new questions of safety or effectiveness. RadOncAI exports an AI-generated DICOM RT Dose object for TPS or DICOM-RT review, while the predicate submits prescription and achievable dosimetric goals to a TPS; both outputs provide dosimetric planning guidance that requires qualified professional review before clinical use.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
	patient populations, anatomic sites, or treatment modalities outside the indications stated above. Caution: Federal law restricts this device to sale by or on the order of a physician.		
Software V&V / Performance Testing	Validation testing was performed using retrospective clinical data from 500 adult head and neck cancer patients from UT Southwestern (UTSW) and multiple Arizona Oncology sites. The final validation cohort included 295 definitive and 205 post-operative/adjuvant cases. The study demonstrated PTV dose equivalence for 9/9 pre-specified PTV tests within +/-300 cGy and OAR non-inferiority for 21/21 pre-specified OAR metrics within +300 cGy at adjusted alpha levels. Additionally, 50 AI-generated cases were independently reviewed by 3 board-certified radiation oncologists for 150 total reviewer assessments, demonstrating 100.0% clinical acceptability and 98.7% OAR achievability. Model-specific assessment was performed separately for definitive and post-operative/adjuvant models.	Validation testing was performed using retrospective clinical data. Non-inferiority of mean OAR dose sparing was demonstrated. For H&N: 19 plans tested, 27 OARs evaluated, non-inferiority demonstrated to 8 Gy. No statistically significant differences in target coverage.	Both devices demonstrated safety and effectiveness through retrospective clinical validation using paired plan comparisons. The subject device's validation is more extensive for head and neck use: larger sample size (500 vs. 19 patients for the predicate head and neck validation), multi-source design, independent clinical review component, and tighter equivalence/non-inferiority margins (3 Gy vs. 8 Gy). These differences support substantial equivalence and do not raise new questions of safety or effectiveness.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Typical Users	Qualified radiation therapy professionals: radiation oncologists, board-certified medical physicists, and certified medical dosimetrists	Medical professionals, including but not limited to, radiation oncologists, medical physicists or physicians	Same. Both devices are intended for the same qualified clinical user population.
Patient Population	Adult patients (aged 18+) with malignant or benign head-and-neck disease. Validated across diverse demographics including multiple cancer subtypes (oropharyngeal, laryngeal, nasopharyngeal, etc.), both definitive and post-operative cases, and patients from academic and community oncology settings.	There are no demographic, regional, or cultural limitations for patients. It is up to the user to determine if the system can be used for a patient.	Substantially Equivalent. The subject device specifies adult head and neck patients; the predicate leaves population determination to the user. The subject device's explicit population definition reflects FDA expectations for AI device labeling and does not raise new safety concerns. Validation data encompasses 500 patients across 2 institutions with diverse demographics (see Performance Study).
Risk Classification	Class II (moderate risk)	Class II (moderate risk)	Same. Both devices carry the same risk classification under 21 CFR 892.5050.
DICOM-RT Compliant	Yes. The device accepts DICOM-RT inputs (CT images, RT Structure sets) and exports DICOM RT Dose objects containing the predicted 3D dose distribution along with DVH metrics for OARs.	Yes. The device accepts and exports DICOM-RT compliant data.	Same. Both devices operate within the DICOM-RT standard for radiation therapy data exchange.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Technological Approach	Locked machine learning algorithm. The subject device uses pre-trained, locked neural network models that generate patient-specific dose predictions from anatomical geometry. The algorithms are not modifiable or editable by the end user. Two locked models are provided: one for definitive treatment cases and one for post-operative (adjuvant) cases.	Locked machine learning algorithm. The predicate uses pre-trained, locked ML models that predict achievable dosimetric goals/objectives for OARs based on patient-specific anatomical geometry. The algorithm is locked prior to clinical use.	Same processing fundamentals. Both devices employ locked machine learning models trained on patient-specific anatomical geometry to generate dosimetric predictions for radiation therapy treatment planning. Both models are locked prior to clinical use and are not modifiable by the end user. The specific model architectures differ (the subject device generates 3D dose distributions; the predicate predicts OAR dosimetric objectives), but both produce dosimetric guidance that is reviewed by qualified professionals before clinical use. This difference in output granularity does not raise new questions of safety or effectiveness, as demonstrated through the subject device's validation testing (500 patients, 2 sites, all primary endpoints met).
Full Treatment Planning System	No. RadOncAI is not a full treatment planning system. It generates preliminary dose predictions that must be transferred to a compatible TPS for plan finalization, optimization, and delivery parameter generation. The device does not perform leaf sequencing, beam modulation, or final dose calculation for treatment delivery.	No. Oncospace works in conjunction with, and does not replace, a treatment planning system (TPS). The user retains full control of the TPS, including finalization of the treatment plan.	Same. Neither device is a full treatment planning system. Both generate dosimetric information intended to be used within the context of an existing TPS workflow, and both require a separate TPS for treatment plan finalization and delivery.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Connected to or Controlling of Radiation Delivery Devices	No. RadOncAI does not interface with treatment machines, record-and-verify systems, or any radiation delivery equipment.	No. Oncospace does not interface with the treatment machines.	Same. Neither device connects to or controls radiation delivery devices. The risk to patient safety is lower than a TPS since both devices only inform the treatment plan and do not interface directly with treatment machines.
Input Data	Patient CT-simulation imaging, clinician-defined planning target volumes (PTVs), and clinician-supplied organs-at-risk (OAR) contours. The device operates on anatomy only; dose prescription and fractionation parameters are determined independently by the treating physician.	Patient CT images, RT Structure sets, and target dose information specified via treatment protocols or user input.	Same fundamental data types. Both devices accept patient CT imaging and structure set data (target volumes and OAR contours) as primary inputs. The subject device operates on anatomy inputs only; the predicate additionally accepts dose prescription parameters via protocols or user input. This difference does not raise new safety concerns — the subject device's dose predictions are based on patient-specific anatomy, and the treating physician independently determines prescription and fractionation, which is standard clinical practice.
Automatic Structure Matching	Yes. Regions of interest are automatically matched when patient data is loaded into the device. The device includes a mandatory confirmation step where clinicians must individually review and approve each structure name mapping before proceeding. Users can manually adjust any mapping.	Yes. Regions of interest are matched as the study is opened in the device. Users can adjust or match to more available regions of interest.	Same. Both devices provide automatic ROI matching with user override capability. The subject device additionally includes a mandatory clinician confirmation step for each structure mapping, providing an additional safety check that ensures structure identification accuracy before dose prediction is initiated.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Plan Review Functionality	Yes. RadOncAI includes built-in visualization of isodose line overlays on CT imaging, DVH display for OAR structures, and dose summation capability. Multi-plan dose comparison (comparing AI output against other plans within RadOncAI) is not supported; comparative evaluation of AI-predicted dose against manual plans is performed in the clinician's TPS.	Contains integrated features and GUI for treatment plan review, including review of isodose lines, DVHs, dose comparison between multiple plans, and dose summation. Provides a user interface for plan evaluation against protocol-based and predicted goals.	Substantially Equivalent. Both devices include built-in plan review features including isodose visualization, DVH display, and dose summation. The predicate additionally supports multi-plan dose comparison within its own interface, while the subject device relies on the clinical TPS for comparative plan evaluation. This difference does not raise new safety concerns — comparative plan review is a standard function of the clinical TPS environment where qualified professionals already conduct plan evaluation as part of routine practice.
Processing and Device Output	Processes input using locked ML models to generate a patient-specific 3D dose distribution, including estimated achievable dose coverage to planning target volumes and estimated achievable sparing of surrounding OARs. Output is exported as a DICOM RT Dose object along with DVH metrics for each OAR structure.	Processes treatment plan data using locked ML models trained on patient-specific anatomical geometry to predict achievable dosimetric goals/objectives for OARs. Supplies dose prescription, delivery method, protocol-based target objectives, and predicted OAR objectives to a TPS to automate initiation of plan optimization.	Same processing fundamentals but different output formats. Both devices use locked ML models operating on patient-specific anatomy to produce dosimetric predictions. The subject device generates a complete 3D dose distribution exported as a DICOM RT Dose object; the predicate predicts OAR dosimetric objectives and supplies them to a TPS. Both outputs serve the same clinical purpose: providing patient-specific dosimetric guidance to support treatment plan optimization. The difference in output granularity does not raise new questions of safety or effectiveness — both outputs require review by qualified professionals and further processing in a TPS before clinical use.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Import Treatment Plans	No. RadOncAI does not import existing treatment plans from third-party systems. The device generates new dose predictions from patient anatomy inputs (CT imaging and structure sets) only.	Yes. Import existing plans from third-party systems to compare dose objectives against templates.	Different. The subject device does not support import of third-party treatment plans; it generates de novo dose predictions from patient anatomy. The predicate supports plan import for comparison against templates. This difference does not raise new safety concerns — it reflects a more focused device scope. The subject device's output is exported to the clinical TPS, where comparison against existing plans can be performed as part of the standard clinical workflow.
Export Plan Information	Yes. The device exports AI-generated dose predictions as DICOM RT Dose objects for review and further optimization by a dosimetrist in a compatible TPS. RadOncAI does not export a final deliverable treatment plan and does not export to a record-and-verify system.	Yes. Can export the selected plan for review and setup by a dosimetrist. Oncospace does not export a final plan; it will not export to a record-and-verify system.	Same. Both devices export preliminary dosimetric information for use in treatment planning workflows and neither exports a final deliverable plan or interfaces with record-and-verify systems. The subject device exports DICOM RT Dose objects; the predicate exports dosimetric objectives in TPS-specific formats. Both export mechanisms serve the same clinical purpose of transferring AI-generated dosimetric guidance into the TPS for further clinical use.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Dose Objective Comparison	RadOncAI displays its AI-predicted DVH metrics for OAR structures. Comparison of AI-predicted dose against manual or alternative plans is not performed within RadOncAI; such comparisons are performed in the clinician's TPS after export.	Yes. Comparison can be done between more than one selected treatment plan. Dose is based on calculated dose and curated, gold-standard treatment plans.	Different. The predicate includes built-in dose comparison against multiple plans and gold-standard templates. The subject device displays AI-predicted DVH metrics and relies on the clinical TPS for comparative dose evaluation. This difference does not raise new safety concerns — dose comparison is a standard function of the clinical TPS, and the subject device's workflow ensures qualified professionals perform comparative evaluation as part of routine plan review in their existing clinical environment.
Isodose Line Display	Yes. RadOncAI displays isodose lines as visual overlays on patient CT imaging, rendered from the 3D dose distribution generated by the AI model. This is a visualization of the predicted dose grid, not an independent dose calculation.	Yes.	Same. Both devices display isodose lines for plan review.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
DVH Display	Yes. RadOncAI calculates dose-volume histogram metrics for each OAR structure by computing dose statistics from the 3D dose distribution against the clinician-supplied OAR contours. These calculated DVH metrics (e.g., mean dose, max dose) are displayed within the device interface.	Yes.	Same. Both devices calculate and display dose-volume histograms for plan review. The subject device computes OAR dose metrics from its 3D dose prediction output; the predicate computes DVH metrics from its dosimetric predictions.
Operating System	Windows, macOS, and Linux	Windows (Client and Server)	Substantially Equivalent. The subject device is compatible with additional operating systems beyond the predicate (macOS and Linux in addition to Windows). Expanded OS compatibility increases clinical deployment flexibility without introducing new safety risks. The core device functionality and clinical output are the same regardless of operating system.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Platform	Client-server architecture. AWS cloud-based hosting with HIPAA Business Associate Agreement (BAA) and encrypted data transfer, as well as clinic-provided on-premises hosting options.	Client-server architecture. Clinic-provided client machines, cloud Windows servers controlled by Oncospace.	Same architecture. Both devices use client-server architecture with cloud-based hosting options. The subject device uses AWS cloud infrastructure with HIPAA BAA compliance and encrypted data transfer; the predicate uses Oncospace-controlled Windows cloud servers. Both approaches provide secure remote processing with appropriate data protection measures. The subject device additionally supports on-premises deployment for institutions requiring local data control.
Workflow Interface and Integration	DICOM-RT based data exchange. Patient data (CT images, RT Structure sets) is imported via DICOM. AI-generated dose predictions are exported as DICOM RT Dose objects, which the clinician manually imports into their clinical TPS (e.g., Eclipse, Pinnacle, or a compatible clinical TPS consistent with the device labeling and V&V testing) for further review, optimization, and plan finalization.	DICOM import, AI prediction planning UI, TPS scripting integration (e.g., Pinnacle scripting language) for streamlined transmission of DICOM files and plan parameters.	Substantially Equivalent. Both devices use DICOM-RT based data exchange for integration with clinical TPS workflows. The predicate additionally includes TPS scripting integration for automated data transfer; the subject device uses manual DICOM export/import. This difference does not raise new safety concerns — manual DICOM import is a standard, well-established workflow in radiation oncology clinics and provides the clinician with direct control over data transfer.

Comparison Item	RadOncAI K253050 (Subject Device)	Oncospace K222803 (Predicate Device)	Comparison Assessment
Acceptable Dose Constraint Tolerance	3 Gy (300 cGy) for both equivalence and non-inferiority margins	8 Gy for H&N non-inferiority margin	The subject device uses a substantially tighter dose tolerance constraint (3 Gy vs. 8 Gy), representing a more conservative standard for establishing device performance. The 3 Gy margin is justified through QUANTEC guidelines, AAPM TG-218 recommendations, NRG/RTOG clinical trial precedent, and published inter-observer variability studies (see Performance Study, Section 2.1).

Machine Learning Approach

RadOncAI is prescription-use software that assists qualified radiation therapy professionals in generating and evaluating initial external-beam radiotherapy treatment plans for adult definitive and post-operative head and neck cases. The device uses a locked, supervised machine-learning model to predict a patient-specific three-dimensional dose distribution from clinician-supplied imaging, structure, and prescription inputs. The output is a preliminary dose prediction and associated DVH/dose metrics for clinical review; it is not a final deliverable treatment plan, does not control radiation delivery, and must be reviewed, revised as needed, and approved by qualified clinical users.

Item	RadOncAI Description
Model version	AI_Model_RT_Unet_v3.1
Learning approach	Supervised deep learning for voxel-level three-dimensional dose prediction
Architecture	Convolutional neural network using a hierarchically dense U-Net / HD U-Net approach with attention mechanisms
Primary inputs	DICOM CT simulation image set, DICOM RT Structure Set contours, prescription dose levels, and treatment intent
Primary outputs	Predicted 3D dose distribution, DVH information, and PTV/OAR dose metrics for clinician review
Clinical use control	Locked model used as a treatment-planning aid with required professional review and approval

RadOncAI Training, Test, and Final Validation Dataset Separation Summary

RadOncAI is a locked supervised machine-learning device for adult head and neck radiation therapy treatment-planning support. Model training, internal validation/tuning, and development testing were completed before final FDA validation. The final FDA validation cohort was assembled separately and was used only to evaluate the locked model.

Prior to selection of the final FDA validation cohort, anonymized patient identifiers associated with the model training/development datasets were identified and excluded from the regulatory validation candidate pool. The final 500-patient FDA validation cohort, including the 50-case clinical QC subset, was therefore patient-level distinct from the model training/development datasets. The final 500-patient validation cohort and the 50-case clinical QC subset were used only after model lock and did not contribute to model training, internal validation/tuning, development testing, model selection, threshold setting, or post-hoc model updates.

StudyDate ranges are provided below as supporting metadata. The primary separation control was patient-level identifier exclusion, not calendar-date separation alone.

Dataset Separation Summary

Dataset	Composition	Use	Separation control
Published model-development datasets	Nguyen et al. (2019) described 120 head and neck patients: 20 held out for testing and the remaining 100 evaluated using 5-fold cross-validation with 80 training and 20 validation patients per fold. Mashayekhi et al. (2023) described 97 definitive head and neck SIB VMAT plans split into 80 training, 12 validation, and 5 testing patients.	Documents development-stage training, validation, and test splitting before the current FDA validation.	The published studies document development-stage splitting. Patient-level exclusion from the final FDA validation cohort was controlled using the curated anonymized identifiers described below.
Curated model-development exclusion manifests	The regulatory data team received anonymized identifiers for 126 definitive model-development cases with CT StudyDate range 2011-07-13 to 2017-02-08 and 119 post-operative model-development cases with CT StudyDate range 2017-02-21 to 2020-10-13.	Identify model-development cases to be excluded before final FDA validation cohort selection.	These identifiers were removed from the regulatory validation candidate pool before the final 500-patient FDA validation cohort was selected. StudyDate ranges were retained as supporting metadata, but separation was controlled at the patient-identifier level.

Dataset	Composition	Use	Separation control
Final FDA validation cohort	500 adult head and neck patient cases. Treatment intent: definitive 295 and post-operative/adjuvant 205. CT StudyDate metadata were available for all 500 cases: UTSW= 397 (2017-02-14 to 2020-10-26) and Arizona Oncology treatment centers=103 (2019-12-05 to 2024-06-25); combined range 2017-02-14 to 2024-06-25.	Final locked-model performance validation using paired AI-generated and reference manual treatment-planning data.	Selected only after model-development identifiers were removed from the regulatory validation candidate pool. Used after model lock only; not used for model training, internal validation/tuning, model selection, development testing, threshold setting, or post-hoc model updates.

Inclusion and Exclusion Criteria

The datasets were defined to match the intended use of RadOncAI and to prevent training/development cases from contributing to final FDA validation.

Dataset	Inclusion criteria	Exclusion criteria
Model training/development datasets	Historical adult head and neck radiotherapy cases with available treatment-planning image/structure information, clinician-defined targets and OARs, prescription information, and clinically delivered or clinically accepted photon treatment-planning dose data appropriate for model development.	Cases outside the adult head and neck intended-use population; cases lacking required imaging, structure, prescription, or dose data; cases not meeting clinical planning-quality requirements for model-development use.
Final 500-patient FDA validation cohort	Adult patients at least 18 years old; head and neck cancer diagnosis within the intended-use population; available CT simulation data and clinician-defined PTV/OAR structures; available paired AI-generated and reference manual treatment-planning dose data; treatment planning performed under established institutional quality-assurance processes; PTV and OAR data sufficient for NRG/RTOG- and QUANTEC-informed endpoint analysis.	Cases categorized as non-head-and-neck; cases missing critical dosimetric data needed for primary endpoint analysis; plans not meeting institutional dose-calculation or planning-quality standards; cases with incomplete clinical or demographic metadata required by the protocol; cases identified as part of the model training/development datasets.
Clinical QC subset	Randomly selected cases from the eligible final 500-patient FDA validation cohort to reflect the distribution of clinical groupings.	No additional QC-specific exclusions were applied after eligibility for the final validation cohort was established.

Non-Clinical Performance Testing

RadOncAI was validated in accordance with a Verification and Validation plan to ensure conformance with established performance criteria.

Software

Software verification and validation was performed for RadOncAI. These activities were performed in accordance with FDA guidance *Content of Premarket Submissions for Device Software Functions (June 2023)* and IEC 62304:2015 Medical device software – Software life cycle processes.

Cybersecurity

InformAI performed cybersecurity testing for RadOncAI in accordance with FDA guidance *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions (February 2026)*.

Summary of Clinical Validation:

Validation testing was performed using retrospective clinical data from 500 adult head and neck cancer patients from UT Southwestern (UTSW) and multiple treatment locations for Arizona Oncology. The final validation cohort included 295 definitive and 205 post-operative/adjuvant cases. The study demonstrated PTV dose equivalence for 9/9 pre-specified PTV tests within +/-300 cGy and OAR non-inferiority for 21/21 pre-specified OAR metrics within +300 cGy at adjusted alpha levels. Additionally, 50 AI-generated cases were independently reviewed by 3 board-certified radiation oncologists for 150 total reviewer assessments, demonstrating 100.0% clinical acceptability and 98.7% OAR achievability. Model-specific assessment was performed separately for definitive and post-operative/adjuvant models.

Validation Dataset

The validation dataset used for final performance testing included 500 adult head and neck patient cases. The final FDA analysis also documented the treatment locations represented in the validation cohort, including three **primary** treatment locations of UTSW Dallas and multiple Arizona Oncology treatment locations, as shown in the table below. Each validation case represents one individual patient CT simulation image set with clinician-defined structures and paired AI-generated and reference manual treatment-planning dose data.

Dataset Element	Count / Description
Individual patient cases / image sets	500
Treatment locations represented	UTSW Dallas: 397; Arizona Oncology - Tucson: 64; Arizona Oncology - Prescott: 36; Arizona Oncology - Goodyear: 1; Arizona Oncology - Phoenix: 1; Arizona Oncology - Green Valley: 1
Clinical organizations	UT Southwestern: 397 (79.4%); Arizona Oncology treatment locations: 103 (20.6%)
Treatment intent	Definitive: 295 (59.0%); post-operative/adjuvant: 205 (41.0%)
Patient/sample relationship	PTV category and OAR metric observations are derived from the same 500 patient-level cases and are not additional independent patients
PTV endpoint family	9 dose-metric tests: D95, D98, and D99 across high-, intermediate-, and low-dose PTV categories

Dataset Element	Count / Description
OAR endpoint family	21 standardized OAR Dmean/Dmax metrics
Clinical QC review	50 AI-generated cases reviewed by 3 board-certified radiation oncologists (150 total assessments)

Demographic Distribution

Demographic characteristics are summarized using the final FDA analysis dataset. Age is presented by prespecified age group; among patients with numeric age recorded, mean age was 64.0 years (SD 12.4; median 65.0; range 19-94 years). Sex, race, and ethnicity were recorded from the source clinical dataset as available.

Category	Level	N	%
Age group	>=70 years	178	35.6%
Age group	60-69 years	151	30.2%
Age group	50-59 years	108	21.6%
Age group	<50 years	62	12.4%
Age group	Unknown	1	0.2%
Sex/Gender as recorded	M	307	61.4%
Sex/Gender as recorded	F	126	25.2%
Sex/Gender as recorded	Unknown/Not Reported	67	13.4%
Race	White	333	66.6%
Race	Unknown/Not Reported	89	17.8%
Race	Black	38	7.6%
Race	Declined	23	4.6%
Race	Asian	10	2.0%
Race	Other	6	1.2%
Race	American Indian or Alaska Native	1	0.2%
Ethnicity	Non-hispanic	348	69.6%
Ethnicity	Unknown/Not Reported	67	13.4%
Ethnicity	Hispanic	53	10.6%
Ethnicity	Declined	23	4.6%
Ethnicity	Unknown	9	1.8%

Category	Level	N	%
Cancer type	Oropharynx	162	32.4%
Cancer type	Oral Cavity	99	19.8%
Cancer type	Other	84	16.8%
Cancer type	Larynx	55	11.0%
Cancer type	Salivary Gland	29	5.8%
Cancer type	Nasal Cavity	26	5.2%
Cancer type	Nasopharynx	17	3.4%
Cancer type	Hypopharynx	16	3.2%
Cancer type	Thyroid	12	2.4%

Summary Test Statistics and Acceptance Criteria

The final validation analysis used pre-specified paired comparisons of AI-generated dose predictions against reference manual treatment plans. PTV coverage was evaluated using equivalence testing with +/-300 cGy margins and family-wise error control across PTV dose categories. OAR sparing was evaluated using one-sided non-inferiority testing with a +300 cGy margin and Bonferroni adjustment across the standardized OAR metrics. This framework reflects the clinical objective that target coverage remains comparable to accepted manual planning while organ-at-risk dose is not meaningfully higher than the paired manual reference plan.

Endpoint	Acceptance Criterion	Final Result
PTV coverage equivalence	Equivalence within +/-300 cGy; adjusted alpha = 0.0167	9/9 tests passed; mean absolute difference 56.0 cGy
OAR dose non-inferiority	Non-inferiority within +300 cGy; adjusted alpha = 0.00238	21/21 metrics passed; AI lower than manual in 20/21 metrics (95.2%); mean absolute difference 137.7 cGy
Independent clinical QC	AI prediction clinically reasonable and useful as a first-pass dose plan with no unresolved AI-attributable safety concerns	Clinical acceptability 100.0%; OAR achievability 98.7%; utility 100.0%; unresolved AI-attributable safety concerns 0

PTV Category	Metric	N Pairs	Mean AI - Manual (cGy)	Result
High Dose PTVs (>=66 Gy)	D95	305	-128.7	Pass

PTV Category	Metric	N Pairs	Mean AI - Manual (cGy)	Result
High Dose PTVs (>=66 Gy)	D98	305	-92.0	Pass
High Dose PTVs (>=66 Gy)	D99	305	-48.9	Pass
Intermediate Dose PTVs (60-65.9 Gy)	D95	291	-79.2	Pass
Intermediate Dose PTVs (60-65.9 Gy)	D98	291	-36.3	Pass
Intermediate Dose PTVs (60-65.9 Gy)	D99	291	16.6	Pass
Low Dose PTVs (<60 Gy)	D95	422	-44.8	Pass
Low Dose PTVs (<60 Gy)	D98	422	-8.7	Pass
Low Dose PTVs (<60 Gy)	D99	422	48.9	Pass

Clinically Meaningful Subgroups and Confounders

The final statistical report evaluated consistency of device performance across clinically meaningful subgroups, including treatment site, treatment intent (definitive versus post-operative/adjuvant), cancer type, and sex. The demographic table above provides the age, race, and ethnicity distributions for the validation cohort. These analyses were interpreted descriptively with forest plots and clinical-margin comparisons rather than as separately powered formal hypothesis tests.

- No systematic degradation in PTV equivalence or OAR non-inferiority was identified across the major clinical subgroups reviewed.
- The paired design compares each AI-generated output with the reference manual plan for the same patient, controlling for patient anatomy and prescription-related confounding.
- OAR missingness reflects anatomy and clinical contour availability rather than device output failure; each OAR metric includes all patients for whom that structure was clinically relevant and available.
- Race and ethnicity distributions are documented for transparency. Some race/ethnicity strata are small, so performance conclusions for those strata should be interpreted descriptively rather than as independently powered subgroup claims.

Equipment and Acquisition Protocols

RadOncAI is designed for CT-based external-beam photon radiotherapy treatment planning in adult head and neck cases. The device accepts DICOM CT simulation scans with 5 mm or less slice thickness and clinician-defined RT Structure Sets. The device description states that RadOncAI is designed to be

interoperable with standard DICOM CT images without contrast, regardless of image vendor, provided image quality is adequate for treatment planning. Clinician-defined PTVs and OAR contours follow NRG/RTOG and RTOG atlas conventions, with dose evaluation performed using PTV coverage metrics and OAR Dmean/Dmax metrics.

Reference Standard / Truthing Process

For final validation, the reference standard was the paired clinically generated manual treatment plan and associated clinician-approved structures for the same patient case. Reference manual plans were created through established clinical treatment-planning workflows and evaluated according to accepted radiation oncology standards, including NRG/RTOG planning protocols and QUANTEC-informed OAR dose assessment. The AI output was then compared against the paired reference plan using patient-level paired statistical testing. This truthing process reflects the intended clinical use: RadOncAI predicts an achievable starting dose distribution from patient anatomy and prescribed targets, while the final deliverable treatment plan remains subject to qualified physician, physicist, and dosimetrist review in the clinical TPS workflow.

Limitations of Use Relevant to ML Performance

- Validated use is limited to adult head and neck radiotherapy treatment-planning support for definitive and post-operative/adjuvant cases.
- The model is not intended for pediatric patients, non-head-and-neck anatomical sites, proton therapy, real-time dose delivery control, or autonomous treatment planning.
- The device is not intended for head and neck skin cancer or brain cancer cases, and the model was not trained on an extensive dataset of benign tumors.
- Outputs may be adversely affected by low-quality CT images, incorrect or non-standard contours, significant artifacts, or anatomy outside the validation experience.

All AI-generated dose predictions require independent clinical review, modification as needed, and approval by qualified radiation therapy professionals. AI-generated outputs must be carefully reviewed and validated by a qualified clinician before being used in treatment planning.

Conclusion

While there are differences noted in the technological characteristics of the proposed system and the predicate device, the differences do not raise different questions of safety or effectiveness. Based on the information provided in this submission, the subject device demonstrates that it is substantially equivalent to the predicate device through the results of clinical performance and results of non-clinical verification and validation.