Oncospace, Inc.
% Sigrid Schoepel
Regulatory Affairs
1812 Ashland Ave., Suite 100k
BALTIMORE MD 21205

February 2, 2023

Re: K222803
Trade/Device Name: Oncospace
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: January 4, 2023
Received: January 5, 2023

Dear Sigrid Schoepel:

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: 2023.02.02 10:53:29 -05'00'

Lora Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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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)*
K222803

Device Name
Oncospace

Indications for Use *(Describe)*
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.

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

I. SUBMITTER

Oncospace, Inc.
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Email: Sigrid.Schoepel@oncospace.com

Contact Person: Sigrid Schoepel
Date Prepared: 2023 February 1

II. DEVICE

Name of Device: Oncospace
Common or Usual Name: System, Planning, Radiation Therapy Treatment
Classification Name: Medical charged-particle radiation therapy system (21 CFR 892.5050)
Regulatory Class: II
Product Code: MUJ

III. PREDICATE DEVICE

Oncospace, K202284

This predicate device has not been the subject of a recall.

IV. DEVICE DESCRIPTION

The Oncospace software supports radiation oncologists and medical dosimetrists during radiotherapy treatment planning. The software includes locked machine learning algorithms. During treatment planning, the Oncospace software works in conjunction with, and does not replace, a treatment planning system (TPS).

The Oncospace software is intended to augment the treatment planning process by:

- allowing the radiation oncologist to select and customize a treatment planning protocol that includes dose prescription (number of fractions, dose per fraction, dose normalization), a delivery method (beam type and geometry), and protocol-based dosimetric goals/objectives for treatment targets, and organs at risk (OAR);

- predicting dosimetric goals/objectives for OARs based on patient-specific anatomical geometry;
- automating the initiation of plan optimization on a TPS by supplying the dose prescription, delivery method, protocol-based target objectives, and predicted OAR objectives;
- providing a user interface for plan evaluation against protocol-based and predicted goals.

Diagnosis and treatment decisions occur prior to treatment planning and do not involve Oncospace. Decisions involving Oncospace are restricted to setting of dosimetric goals for use during plan optimization and plan evaluation. Human judgement continues to be applied in accepting these goals and updating them as necessary during the iterative beam optimization process. Human judgement is also still applied as in standard practice during plan quality assessment; the protocol-based OAR goals are used as the primary means of plan assessment, with the role of the predicted goals being to provide additional information as to whether dose to an OAR may be able to be further lowered.

When Oncospace is used in conjunction with a TPS, the user retains full control of the TPS, including finalization of the treatment plan created for the patient. Oncospace also does not interface with the treatment machines. The risk to patient safety is lower than a TPS since it only informs the treatment plan, does not allow region of interest editing, does not make treatment decisions, and does not interface directly with the treatment machine or any record and verify system.

Oncospace's OAR dose prediction approach, and the use of predictions in end-to-end treatment planning workflow, has been tested for use with a variety of cancer treatment plans. These included a wide range of target and OAR geometries, prescriptions and boost strategies (sequential and simultaneous delivery). Validity has thus been demonstrated for the range of prediction model input features encountered in the test cases. This range is representative of the diversity of the same feature types (describing target-OAR proximity, target and OAR shapes, sizes, etc.) encountered across all cancer sites. Given that the same feature types will be used in OAR dose prediction models trained for all sites, the modeling approach validated here is not cancer site specific, but rather is designed to predict OAR DVHs based on impactful features common to all sites. The software is designed to be used in the context of all forms of intensity-modulated photon beam radiotherapy. The planning objectives themselves are intended to be TPS-independent: these are instead dependent on the degree of organ sparing possible given the beam modality and range of delivery techniques for plans in the database. To facilitate streamlined transmission of DICOM files and plan parameters Oncospace includes scripts using the treatment planning system's scripting language (for example, Pinnacle).

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Oncospace subject device is a software-only medical device that performs the same functions in the Oncospace predicate device. The following differences exist between the subject and predicate devices:

- The machine-learning algorithm has been generalized to allow training, modeling, and testing of dosimetric predictions for treatment target/organ-at-risk geometries and a head and neck model has been developed and added to the subject device.
- The plan-matching method (a non-ML based method for dosimetric predictions) that was in place in the predicate device for head & neck, thoracic, and pancreas geometries has been removed.

Note: The predicate device and subject device algorithms, and any future algorithm updates, are locked prior to clinical use.

Element	Subject	Predicate	Conclusion
Device Name	Oncospace	Oncospace	Identical
510(k) Owner	Oncospace, Inc.	Oncospace, Inc.	
510(k) Number	K222803	K202284	
Product Code	MUJ	MUJ	Identical
Product Name	System, Planning, Radiation Therapy Treatment	System, Planning, Radiation Therapy Treatment	Identical
Intended Use	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).	Oncospace is used to configure and review radiotherapy treatment plans for a patient with malignant or benign disease in the prostate, thoracic, pancreas, or head & 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).	Removed thoracic and pancreas since plan-matching methodology was removed. Prostate, head, and neck use the ML models.

Element	Subject	Predicate	Conclusion
	This device is for prescription use by order of a physician.	This device is for prescription use by order of a physician.	
Operating System	Windows/Web-browser	Windows/Web-browser	Identical
Platform	Client-Server (Clinic-provided client machines, cloud Windows servers controlled by Oncospace)	Client-Server (Clinic-provided client machines, cloud Windows servers controlled by Oncospace)	Identical
DICOM-RT Compliant	Yes	Yes	Identical
Full Treatment Planning System	No	No	Identical
Connected to or Controlling of Radiation Delivery Devices	No	No	Identical
Typical Users	Medical professionals, including but not limited to, radiation oncologists, medical physicists or physicians.	Medical professionals, including but not limited to, radiation oncologists, medical physicists or physicians.	Identical
Patient Population	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.	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.	Identical
Environment	The system can be used in a hospital environment or in a doctor's office.	The system can be used in a hospital environment or in a doctor's office.	Identical
JPEG image support	Yes	Yes	Identical
Import Treatment Plans	Yes. Import existing plans from third-party systems to compare dose objectives against templates.	Yes. Import existing plans from third-party systems to compare dose objectives against templates.	Identical

Element	Subject	Predicate	Conclusion
"Template" Treatment Plans	Yes. Factory-default plans with dose goals exist and users can configure a dose template.	Yes. Factory-default plans with dose goals exist and users can configure a dose template.	Identical
Automatic Initial Tumor Selection	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.	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.	Identical
Dose Objective Comparison	Yes. Comparison can be done between more than one selected treatment plan. Dose is based on calculated dose and curated, gold-standard treatment plans.	Yes. Comparison can be done between more than one selected treatment plan. Dose is based on calculated dose and curated, gold-standard treatment plans.	Identical
Image Viewer Capabilities	Yes. Display, pan, zoom, scroll, windowing, viewport layout.	Yes. Display, pan, zoom, scroll, windowing, viewport layout.	Identical
Calculate and Display Isodose Lines	Yes	Yes	Identical
Calculate and Display Dose Volume Histograms	Yes	Yes	Identical
Compare Dose from Multiple Plans	Yes	Yes	Identical
Dose Summation/ Treatment-Over-Time Data	Yes	Yes	Identical
Plan Review	Yes. Contains features for review of isodose lines, review of DVHs, dose comparison and dose summation.	Yes. Contains features for review of isodose lines, review of DVHs, dose comparison and dose summation.	Identical

Element	Subject	Predicate	Conclusion
Export Plan Information	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.	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.	Identical

VII. PERFORMANCE DATA

The following verification and validation testing results (performance data) are provided in support of the substantial equivalence determination. Since this is a software-only medical device that does not control other devices the performance data do not include biocompatibility, electrical safety, electromagnetic compatibility, mechanical, acoustic, or animal testing.

The verifications tests met all system requirements and acceptance criteria which address clinical, standard user interface, and cybersecurity requirements for the Oncospace device.

The validation testing was performed using retrospective clinical data. The Oncospace device's purpose is to reduce the number of iterations necessary to achieve a clinically viable and deliverable radiation treatment plan. A validation trial was designed to demonstrate non-inferiority of mean organ-at-risk (OAR) dose sparing, an indicator of plan quality. This comparison of OAR sparing is only valid if target coverage is maintained, so this comparison was also made. Alongside these dosimetric comparisons, comparison of number of plan optimization iterations required to arrive at a clinically acceptable plan was carried out as a measure of any gain in planning efficiency. Sample sizes were determined by estimating variance in mean OAR dose so that the trial would have 80% power at a significance level of 0.05 and a non-inferiority margin of 10 Gy.

A heterogenous retrospective set of traditionally planned radiation treatment plans for prostate (n=13, 10 different prescriptions) and head & neck (n=19, 12 different prescriptions) cancers was used for validation. Mean doses were compared for 7 OARs for prostate and 27 OARs for head & neck.

- Prostate OARs for clinical performance testing: bladder, left and right femur, rectum, sigmoid colon, penile bulb, and bowel bag. For the prostate performance 1336 treatment plans were used for model development and internal validation (split 80/20), 13 plans were used for clinical performance testing.
- Head and Neck OARs for clinical performance testing: brain, brainstem, spinal cord, left and right cranial nerve VIII (acoustic nerve) , left and right parotid glands , left and right eyes, left and right lens , left and right optic nerve, optic chiasm, oral cavity, soft palate, glottis, cricopharyngeus, esophagus, sublingual gland, mandible bone, left and right submandibular glands, left and right cochlea, thyroid gland, and pharyngeal constrictor muscle(s). For the head

and neck performance 796 treatment plans were used for model development and internal validation (split 80/20), 19 plans were used for clinical performance testing.

The Oncospace plan mean dose was statistically significantly lower for 2 OARs for prostate and 1 OAR for head & neck, and there were no statistically significant differences in mean dose for any of the remaining 5 OARs for prostate and 26 OARs for head & neck. The trial demonstrated non-inferiority of mean OAR dose to 5 Gy for prostate and 8 Gy for head & neck. There was no statistically significant difference in target coverage between clinical plans and plans created with use of the Oncospace system. Out of all the plans tested, no plan required more optimization iterations using Oncospace versus using traditional radiation treatment planning clinical workflow, and the average number of iterations was reduced by 77% using Oncospace.

Conclusion

Verification and validation (including performance testing) was conducted in accordance with FDA guidance recommendations to confirm the device design met all specifications, user needs, and was acceptable to qualified clinical users. Oncospace has passed all the tests and the provided testing results demonstrate safety and effectiveness as compared to the predicate device. It is therefore concluded that Oncospace is substantially equivalent to the predicate device.

VIII. CONCLUSIONS

The subject Oncospace device is similar in intended use and functionality to the predicate Oncospace device. Oncospace has the same technological characteristics and features as the previously cleared device and does not raise new questions of safety or efficacy compared to the predicate device as demonstrated through the system design and testing.

Non-clinical and clinical verification, validation, and performance testing was conducted to confirm the device design met user needs and specifications and was acceptable to qualified clinical and non-clinical users. Oncospace has passed the verification and validation tests and provided clinical performance testing results with a library clinical dataset in order to demonstrate safety or effectiveness as compared to the predicate device. It is therefore concluded that the subject Oncospace device is substantially equivalent to the predicate Oncospace device.