Oncospace, Inc.
℅ Praveen Sinha
CEO
1812 Ashland Avenue, Suite 100k
BALTIMORE MD 21205

March 12, 2021

Re: K202284
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: February 4, 2021
Received: February 8, 2021

Dear Praveen Sinha:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202284

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, 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). 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: Praveen.sinha@oncospace.com

Contact Person: Praveen Sinha
Date Prepared: March 12, 2021

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

RT Elements, K142108

This predicate has been subject to three class 2 device recalls, one of which is still open (Z-1205-2019).

IV. DEVICE DESCRIPTION

The Oncospace software supports radiation oncologists and medical dosimetrists during radiotherapy treatment planning for prostate, thoracic, pancreas, and head & neck cases. The software includes machine learning algorithms that are locked during use. 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.

The central value proposition of the Oncospace software is as follows: In standard clinical practice, OAR dose goals are set according to dosimetric criteria included in treatment planning protocols. These criteria represent a consensus for a population of patients for whom the protocol is applicable. The actual achievable dose levels for an individual patient are however dependent on the patient's individual anatomical geometry, such as the location of each OAR relative to the target volume(s), and size of the target(s) and OARs. Achievable OAR dose levels may be lower than protocol goals, in which case Oncospace can help ensure that opportunities for further OAR dose reduction are not missed; on the other hand the protocol goals may be lower than achievable, in which case Oncospace can help prevent inappropriately aggressive goals for one OAR from compromising both target dose coverage and reduction of dose to other OARs. Furthermore, the setting of achievable dosimetric objectives at the outset of plan optimization can help shorten the iterative process of objective adjustment typically followed by the dosimetrist to bring the plan to a state suitable for review by the radiation oncologist. Oncospace uses a database of approved treatment plans to derive individualized OAR dose goals, via comparison of the current patient's anatomical geometry to that for applicable patients in the database.

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 has been tested for use in prostate, thoracic, pancreas, and head & neck patient plans. In the current software release, static machine learning models are used for prostate plan predictions, and statistical/database lookup methods are used for thoracic, pancreas, and head & neck plan predictions.

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. Oncospace includes a supporting interface with the Pinnacle TPS using its scripting interface to facilitate streamlined transmission of DICOM files and plan parameters.

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, 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). This device is for prescription use by order of a physician.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Oncospace is a software-only medical device that performs the same functions in the predicate, RT Elements, device. The subject Oncospace device is similar to the predicate RT Elements device:

- Client-server platform
- DICOM-RT compliant
- Does not control or connect to radiation delivery devices
- Import treatment plans
- Evaluate treatment options
- Export plan information
- No restrictions on patient population

The following differences exist between the subject and predicate devices:

- Oncospace includes a browser-based interface
- Export from Oncospace is for import into treatment planning systems

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 is meant to reduce the number of iterations necessary to achieve a clinically viable and deliverable radiation treatment plan. A retrospective set of traditionally planned radiation treatment plans for prostate, thoracic, pancreas, and head and neck cancers were used to compare the number of iterations necessary without using Oncospace (the number of iterations when the plan was originally approved were used) to the number of iterations to get to a clinically viable and deliverable plan when using Oncospace as part of the treatment planning workflow. Out of all the plans tested, only one plan took more iterations (one more) using

Oncospace versus using traditional radiation treatment planning clinical workflow, and the average number of iterations was reduced by almost two thirds 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. 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 RT Elements device. Oncospace has the same technological characteristics and features as the previously cleared device and does not raise new questions of safety or efficacy 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. It is therefore concluded that the subject Oncospace device is substantially equivalent to the predicate device.