May 14, 2026

SeeTreat Pty Ltd
Eric Qin
VP of Regulatory and Clinical Affairs
320 Pitt Street
Sydney, NSW 2000
Australia

Re: K253078
Trade/Device Name: ART.1-US
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: April 1, 2026
Received: April 1, 2026

Dear Eric Qin:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253078

Device Name
ART.1-US

Indications for Use *(Describe)*
ART.1-US is a software as a medical device intended to support the treatment re-plan process for cancer patients receiving radiation therapy.
ART.1-US calculates delivered dose and contours based on cancer patients' daily volumetric images, in addition to displaying and reporting relevant metrics. ART.1-US allows for the comparison of dosimetry between the delivery of each fraction and the treatment plan in radiation oncology.
ART.1-US is intended for use by trained medical professionals as a decision support tool to aid the treatment re-plan process.
ART.1-US is indicated for adult Head & Neck cancer patients undergoing radiation therapy.

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

K253078

1.0 Submitter details

Submitter name:	SeeTreat Pty Ltd
Submitter address:	320 Pitt Street, Sydney, NSW, 2000, Australia
Contact person:	Eric Qin
Date summary prepared:	1 April 2026
Contact number:	+61 413 142 856

2.0 Device information

2.1 Regulatory information

Regulation number	Device type	Device Class	Product code	Classification panel
21 CFR 892.5050	Medical Charged-Particle Radiation therapy System	Class II	MUJ	Radiology

2.2 Device name

ART.1-US

2.3 Intended use

ART.1-US is a software as a medical device intended to support the treatment re-plan process for cancer patients receiving radiation therapy.

ART.1-US calculates delivered dose and contours based on cancer patients' daily volumetric images, in addition to displaying and reporting relevant metrics. ART.1-US allows for the comparison of dosimetry between the delivery of each fraction and the treatment plan in radiation oncology.

ART.1-US is intended for use by trained medical professionals as a decision support tool to aid the treatment re-plan process.

2.4 Indications for use

ART.1-US is a software as a medical device intended to support the treatment re-plan process for cancer patients receiving radiation therapy.

ART.1-US calculates delivered dose and contours based on cancer patients' daily volumetric images, in addition to displaying and reporting relevant metrics. ART.1-US allows for the comparison of dosimetry between the delivery of each fraction and the treatment plan in radiation oncology.

ART.1-US is intended for use by trained medical professionals as a decision support tool to aid the treatment re-plan process.

ART.1-US is indicated for adult Head & Neck cancer patients undergoing radiation therapy.

2.5 Contraindications

ART.1-US is not intended to be used:

- for patients outside the specified cohorts (non-Head & Neck cancer patients)
- Paediatric Patients

ART.1-US is incompatible with:

- Non-CT planning data
- Non-CBCT (Cone Beam Computed Tomography) daily treatment data
- Non-photon treatments

2.6 Device description

ART.1-US is a software as a medical device (SaMD) that streamlines adaptive radiation therapy by automatically calculating the delivered dose using the patient's daily anatomical images.

ART.1-US consists of a single software package with two main subcomponents:

- User interface
- Backend.

The backend houses key algorithms which are responsible for image registration and dose calculations.

2.6.1 Image registration module

Image registration module in ART.1-US calculates a Deformable Vector Field (DVF) that maps the planning CT image to the CBCT image taken on the treatment day to create a synthetic CT.

The synthetic CT will have the resolution and Field of View of the CT whilst representing the anatomy of the CBCT image.

ART.1-US propagates the contours of the relevant structures by mapping the contours manually drawn by physicians and stored in the DICOM structure set using the same DVF that maps from CT to CBCT. These propagated contours can be overlaid upon the dose to facilitate subsequent dose metrics calculation for defined structures.

2.6.2 Dose calculation module

The dose calculation module is responsible for calculating the dose delivered to the patient on the day using the Collapsed Cone Convolution technique. It uses the synthetic CT generated from image registration module as well as the treatment plan parameters specified in the DICOM radiation therapy plan.

The dose-volume histogram of each relevant structure and dose metrics as specified by the clinic are calculated by ART.1-US using the propagated contours and the delivered total dose.

2.6.3 Device inputs and outputs

Device inputs:

- DICOM CT image (planning image): the patient CT used for planning
- DICOM Radiotherapy Structure sets: contours used for planning

- DICOM Radiotherapy Dose: planned dose
- DICOM Radiotherapy Plan: radiation parameters to deliver the planned Dose
- DICOM Cone Beam CTs: patient on-treatment reconstructed cone beam CTs
- DICOM SRO: an IGRT file representative of spatial transformations for the patient position at treatment delivery

Device outputs:

- Delivered dose
- Daily structure contours
- Dosimetric analytics for configured structures
- Dose deviation indicator of each structure's result based on configuration settings (comparison between delivered and planned dose)
- Reports summary of all the above

3.0 Predicate device

Predicate device name:	ART-Plan
Manufacturer:	TheraPanacea
Regulation number:	21 CFR 892.5050
Classification:	Class II
Product code:	MUJ
Classification panel:	Radiology
510(k) clearance:	K232479

4.0 Summary of substantial equivalence

	Proposed device (ART.1-US)	**Predicate device (ART-Plan)**	**Comparison**
Regulation name	Medical Charged-Particle Radiation Therapy System	Medical Charged-Particle Radiation Therapy System	Equivalent
Regulation Number	21 CFR 892.5050	21 CFR 892.5050	Equivalent
Device Classification	Class II	Class II	Equivalent
Classification Product Code	MUJ	MUJ	Equivalent
Intended use & Indications for use	ART.1-US is a software as a medical device intended to support the treatment re-plan process for cancer patients receiving radiation therapy. ART.1-US calculates delivered dose and contours based on cancer patients' daily volumetric images, in addition to displaying and reporting relevant metrics. ART.1-US allows for the comparison of dosimetry	ART-Plan is a software intended to be used by trained clinicians who are familiar with radiation therapy, such as medical physicists, medical dosimetrists and radiation oncologists. The software consists of different applications, each used for specific purposes at a different phase of radiation treatment planning. ART-Plan offers the following tools to aid in the	Similar: both the proposed device and the predicate are intended to provide outputs which can be used to support offline treatment re-plan decisions. There are minor differences in

	between the delivery of each fraction and the treatment plan in radiation oncology. ART.1-US is intended for use by trained medical professionals as a decision support tool to aid the treatment re-plan process. ART.1-US is suitable for adult Head & Neck cancer patients undergoing radiation therapy.	workflow of radiotherapy treatment: • Multi-modal visualization and rigid- and deformable registration of anatomical and functional images such as CT, MR, PET-CT, 4D-CT, CBCT and synthetic-CT generated from CBCT • Display of fused and non-fused images to facilitate the comparison and delineation of image data by the user • Manual generation, modification and semi-automatic generation of contours for the regions of interest • Automatic generation of contours for organs at risk and healthy lymph nodes, based on medical practices, on medical images such as CT and MR images • Generation of synthetic-CT from MR images for supported anatomies • Generation of synthetic-CT from CBCT images for supported anatomies • Dose computation on CT and/or synthetic-CT images for external beam irradiation with photon beams • Assisted CBCT-based off-line adaptation decision-making for supported anatomies The device is intended to be used in a radiation therapy clinical setting, by trained	the supported image formats. Both devices are intended for professional use only.

		professionals only.	
Target population	Adult cancer patients	Adult cancer patients	Equivalent
Intended User	Trained clinicians	Trained clinicians	Equivalent
Key device inputs	CT, CBCT	CT, CBCT, MR, PET-CT, 4D-CT	Similar: both devices support CT and CBCT as inputs. There are some minor differences in the support of other image file formats.
Technological characteristics	Image registration/contouring: Propagates existing clinician-drawn contours using Rigid and Deformable image registration for the purposes of replanning/recontouring. Dose calculation: Dose computation on synthetic-CT images for external beam irradiation with photon beams.	Image registration/contouring: Rigid and deformable automatic and manual initialization registration for the purposes of replanning/recontouring. AI/Deep-learning based automatic segmentation of OARs and healthy lymph nodes. Dose calculation: Dose computation on CT and/or synthetic-CT images for external beam irradiation with photon beams.	Similar: both devices can perform image registration using deformable image registration techniques to propagate existing contours. Note that the proposed device does not generate contours or perform image segmentation using AI. Both devices calculate dose from synthetic-CTs. These minor technological differences do not increase the safety risks for the proposed device.
Off-line re-plan decision support	Supported	Supported	Equivalent

Based on the above comparison and the Appendix A of the FDA guidance titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" July 28 2014, it can be concluded that the proposed device is substantially equivalent to the predicate device.

5.0 Performance tests

The following key performance tests were performed to evaluate the safety and effectiveness of the proposed device:

Test	Description	Results
Usability summary report	This document summarizes all usability testing activities conducted per IEC62366-1, including both formative and summative tests.	Pass
Algorithm performance verification	This is a bench test utilizing both phantom and preliminary retrospective clinical data to evaluate the performance of the dose engine, image registration, analysis time and compatibility of the proposed device.	All test results passed the following acceptance criteria: • Median ≥ 90% of voxels passing gamma criteria of 3%/2mm • >95% of voxels passing gamma criteria of 3%/2mm for water phantom cases • >90% of voxels passing gamma criteria of 3%/2mm for air-slab phantom cases • Median Target Registration Error between CBCT and CT < 3 mm
Algorithm performance verification – quantitative contour evaluation	This is a bench test which evaluates the proposed device's ability to propagate contours using quantitative metrics such as DSC and ASSD.	All test results passed the following acceptance criteria: • Mean DSC ≥ 0.8 or Mean DSC ≥ Inter-rater DSC – 0.05 • Mean ASSD ≤ 3mm or Mean ASSD ≤ Inter-rater ASSD + 1mm
Retrospective Clinical Data Analysis	A study which uses retrospective patient data to evaluate all key processes of the proposed device, including image registration, synthetic CT generation, contour	All test results passed the following acceptance criteria: Image registration:

	propagation, dose calculation as well as end-to-end device output.	• Median TRE < max voxel dimension sCT quality: • Median γ pass rate of ≥90% using 3%/2mm tolerance • The mean Jacobian determinant of the DVF used in the DIR between the pCT and the sCT shall be 1 ± 5% • DVH parameters comparison between sCT and pCT shall be within 5% of the prescription dose for at least 80% of cases Contour evaluation: • ≥80% of cases shall be deemed by clinicians as acceptable or acceptable with minor modifications Dose calculation: • Median gamma pass rate of ≥90% using 3%/2mm tolerance • The dosimetric difference between the proposed device and a reference TPS shall be within 5% of the prescription dose for at least 80% of cases End-to-end testing: • Median gamma pass rate of ≥90% using 3%/2mm tolerance. • The dosimetric difference between the proposed device and a reference TPS shall be within 5% of the prescription dose for at least 80% of cases

Software verification and validation	Unit, integration, and system-level verification and validation conducted in accordance with IEC 62304 and the FDA guidance "Content of Premarket Submissions for Device Software Functions". Documentation is at an enhanced level.	Pass
Cybersecurity	Cybersecurity risk assessment and penetration testing have been conducted in accordance with AAMI TIR57 Principles for medical device security – risk management and the FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"	Pass

6.0 Animal studies

No animal studies were conducted.

7.0 Clinical studies

No prospective clinical studies were conducted.

8.0 Conclusion

Based on the test results and comparative analysis, the SeeTreat ART.1-US device demonstrates substantial equivalence to the identified predicate device.

The performance testing demonstrates that SeeTreat ART.1-US meets all applicable safety and effectiveness requirements. The device performs within its specified acceptance criteria and maintains the same risk–benefit profile as the predicate.

Therefore, the SeeTreat ART.1-US device is substantially equivalent to the predicate device and is as safe and effective for its intended use when operated according to the labeling instructions.