July 2, 2026

Oncosoft. Inc.
Boram Kim
RA/QA Manager
37, Myeongmul-Gil, Seodaemun-Gu
Seoul, 03776
Republic of Korea

Re: K260528
Trade/Device Name: OncoStudio
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: June 2, 2026
Received: June 2, 2026

Dear Boram Kim:

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,

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260528

Please provide the device trade name(s).

OncoStudio

Please provide your Indications for Use below.

OncoStudio is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.
It also supports the review, processing, and analysis of medical imaging and radiotherapy information within the radiation therapy planning workflow.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

February 14, 2026

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Oncosoft Inc.,
- Address: 37, Myeongmul-gil, Seodaemun-gu, Seoul, Republic of Korea (03776)
- Contact Name: Boram Kim
- Telephone No.: +82-10-6305-7428
- Email Address: kbrstar@oncosoft.io

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

510(k) Number	K260528
Trade/Device/Model Name	OncoStudio
Device Classification Name	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050
Classification Product Code	QKB
Device Class	Class II
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

Predicate Device

510(k) Number	K242994
Trade/Device/Model Name	OncoStudio
Device Classification Name	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050
Classification Product Code	QKB
Device Class	Class II
510(k) Review Panel	Radiology

These predicate devices have not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

OncoStudio is intended for use by qualified healthcare professionals in radiation oncology to support the preparation and evaluation of radiotherapy treatment planning. It is indicated for use in the import, visualization, and processing of CT, MR, 4DCT, PET/CT images and associated DICOM images.

OncoStudio provides tools for:

- Receive, transmit, store, retrieve, display, and process medical images and DICOM objects
- Manual and deep learning based automatic contouring
- Visualization of RT dose distributions
- Dose accumulation
- Generation and analysis of dose-volume histograms (DVHs)
- Image fusion and registration

The DICOM-compliant structure set data generated in OncoStudio can be exported to treatment planning systems for further use in radiotherapy planning.

It is also designed to automatically contour regions of interest within CT and MR images acquired from DICOM-formatted CT and MR imaging devices, using a segmentation model developed through artificial intelligence. The segmented output can be used in the planning of radiation therapy.

The AI-driven image segmentation algorithm is based on a network architecture refined using a CNN deep learning technology. The software complies with the DICOM standard, ensuring compatibility with Picture Archiving and Communication Systems (PACS).

6. Indications for use [21 CFR 807.92(a)(5)]

OncoStudio is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

It also supports the review, processing, and analysis of medical imaging and radiotherapy information within the radiation therapy planning workflow.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of the subject device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the subject device and the predicate devices:

[Table 1. Comparison of Proposed Device to Predicate Device and Reference Device]

Item	Subject Device	Predicate Device
	OncoStudio	OncoStudio
Regulation Name	Medical Image Management And Processing System	Medical Image Management And Processing System
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Product Code	QKB	QKB
Class	II	II
510k Number	K260528	K242994
Indication for Use	**OncoStudio is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.** **It also supports the review, processing, and analysis of medical imaging and radiotherapy information within the radiation therapy planning workflow.**	OncoStudio provides deep-learning-based automatic contouring to organs at risk in DICOM-RT format from CT images. This software could be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed. • Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis • Generates DICOM-RT structure of contoured objects • Manual Contouring • Receive, transmit, store, retrieve, display, and process medical images and DICOM objects
Regions of Interest(ROIs)	**CT Model: 221(Updated)** **MR Model: 115(New added)**	CT Model: 190
Operating System	Local deployment on Windows	Local deployment on Windows
Image Format	DICOM	DICOM

General Functions	• Receive, transmit, store, retrieve, display, and process medical images and DICOM objects • Manual and deep learning based automatic contouring • **Visualization of RT dose distributions** • **Dose accumulation** • **Generation and analysis of dose-volume histograms (DVHs)** • **Image fusion and registration**	1) Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis 2) Generates DICOM-RT structure of contoured objects 3) Manual Contouring 4) Receive, transmit, store, retrieve, display, and process medical images and DICOM objects
Algorithm	Deep Learning	Deep Learning
Compatible Modality	CT, **MR, 4DCT, PET/CT** Images.	CT Images. DICOM RTSTRUCT for output
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM 3.0 compliance required.
Compatible Treatment Planning System	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.
Patient Population	Adult only	Adult only

The intended use of the predicate device and the subject device are equivalent. Both devices are intended to aid users to contour the body structure using artificial intelligence algorithm that can be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

A detailed comparison shows the subject device is substantially equivalent in indications for use, image format, general functions, algorithm, segmentation of organs, workflow, compatible scanner models, compatible treatment planning system and patient population to the predicate device. The differences between the subject and the predicate devices do not raise any new questions regarding safety and effectiveness.

8. Non-Clinical Test summary

The following data were provided in support of the substantial equivalence determination:

1) Software Validation

The OncoStudio contains basic document level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- “Content of Premarket Submissions for Device Software Functions,” dated June 14, 2023.

2) Performance characteristics

A standalone performance test was conducted to evaluate the contouring capabilities of OncoStudio for structures of interest.

All data used for this standalone performance evaluation were entirely independent from the data used during product development or training.

The dataset included diverse ethnic groups, ensuring that the performance results reflect generalizability without significant differences among ethnicities.

Ground truth segmentations were created by three experienced radiation oncologists, following established international clinical guidelines.

For the structures of interest present in OncoStudio, the mean Dice Similarity Coefficient (DSC) and the 95%Hausdorff Distance (HD95) were evaluated for each body region (Head & Neck, Thorax, Abdomen, and Pelvis) and were required to meet the predefined performance acceptance criteria.

Data classified as unknown in the evaluation dataset indicate cases where information could not be identified from the image labels; these data were reviewed according to internal procedures and used for evaluation.

a) Training

[CT Model training dataset]

We collected CT image data for CT model from datasets of source(OneMedNet, Yonsei Severance Hospital), and other datasets(University Hospital Basel, Basel, Switzerland mainly and other publicly available datasets minorly). OneMedNet is a purchased set of CT data, mainly comprised of U.S.A. population. Yonsei Severance Hospital is located in South Korea, and we collected mainly Eastern population data from this source. The University Hospital Basel data is known as TotalSegmentator dataset, which is open for public at this moment.

The collected data comprises a total of 2,912 dataset, consisting of 249 datasets from the US, 1,557 from Korea, and 1,106 from other datasets.

[MR Model training dataset]

We collected MR image data for MR model from datasets of source(Yonsei Severance Hospital), and other datasets(University Hospital Basel, Basel, Switzerland mostly and other publicly

available datasets).

The collected data comprises a total of 1,002 images, consisting of 441 images from Korea, and 561 images from other datasets.

The data was constructed with various ethnics (White, Black, Asian, Hispanic, Latino, African, American, etc.), and the training model can be obtained by performing generalization without differences according to ethnicity.

For evaluation, we created a test dataset that was not involved in any kind of training process. The splitting was performed at the patient level to ensure that images from the same patient were not present in more than one dataset. A comprehensive audit was conducted to confirm the integrity of the data-splitting process and ensure that no patient overlap occurred between datasets.

b) Ground Truthing

The ground truth annotations for the dataset of Yonsei Severance Hospital(Korea), OneMedNet, FSM, TCIA, MSTT-199, MRISegmenter, and ProstateX (U.S.A), and other publicly available datasets were established by three different radiation oncologists with 3-20 years of clinical practice (See Appendix 1 for their detailed CVs) following RTOG and clinical guidelines using manual annotation. The radiation oncologists included associate professor, assistant professor, and radiation oncologist resident from two institutions (Yonsei Cancer Center, Samsung Seoul Hospital)

- Ground Truthing process
  - First, the 1 radiation oncologist manually delineated the ROIs
  - Second, segmentation results generated by 1 radiation oncologist are sequentially edited and confirmed by 2 radiation oncologists. In this editing process, the first radiation oncologist makes corrections, and the corrected results are received and finalized by another radiation oncologist.

In case of Totalsegmentator(University Hospital Basel, Basel, Switzerland) dataset for CT model, the dataset is public data comprising 104 anatomical structures. A total of1,368 CT images were randomly sampled from the years 2012, 2016, and 2020 from the University Hospital Basel through picture archiving and communication system (PACS). The Nora Imaging Platform was used for manual segmentation and further refinement of generated segmentations for ground truth. Segmentation was supervised by two physicians with 3 (M.S.) and 6 years (H.B.) of experience in body imaging, respectively.

In case of the MRI dataset, the Totalsegmentator(University Hospital Basel, Basel, Switzerland) dataset comprises 80 anatomical structures. A total 616 MRIs were retrospectively sampled from the years 01/2011 to 01/2023 from the University Hospital Basel(n=576), AMOS22 challenge test set(n=20), CHAOS challenge test set(n=20). Segmentation was performed and reviewed by two board-certified radiologists with 12 (T.A.D.) and 7 (H.C.B.) years of experience, using an iterative learning approach.

c) Conclusion of performance testing

To validate the A.I generated segmentation performance of OncoStudio, we have performed DSC(Dice Similarity Coefficient) and 95% Hausdorff Distance tests.

The performance evaluation test results confirmed that the contouring performance of the OncoStudio AI model for CT and MR images meets the predefined performance criteria.

It is known that DSC metrics are sensitive to structure volume of structures of interest, so we set the different pass criteria for three size categories similar to the predicated device. The test result showed that all segmentation performances for proposed ROIs are statically acceptable for pre-established criteria considering standard deviation.

According to previous studies, the 95% Hausdorff Distance test has shown different results depending on the anatomical region. Based on this, the results of the this performance test have met the appropriate criteria for each case. Therefore, based on the performance test, the proposed device OncoStudio is determined to be safe and effective.

3) Cybersecurity

• “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”, on September 27, 2023

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the subject device and the predicate device (K242994) that would adversely affect the safety or effectiveness of the product. The subject device is substantially equivalent to the predicate device with respect to its indications for use and technological characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

The subject device is based on the same fundamental technological principles as the predicate device (K242994) and has the same intended use in supporting clinicians with automatic segmentation for radiotherapy planning. Compared to the predicate device, the subject device includes the addition of certain general software functionalities and an expansion of the auto-

segmentation feature to support additional imaging modality(ies) and an extended list of Regions of Interest (ROIs). These modifications do not alter the core segmentation approach or intended clinical workflow and do not raise new questions of safety and effectiveness. Verification, validation, and performance testing were conducted to confirm that the updated functionalities maintain clinically acceptable segmentation performance. Therefore, the subject device is substantially equivalent to the predicate device.

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the OncoStudio is substantially equivalent in safety and effectiveness to the predicate device as described herein.