November 25, 2025

RAY Co., Ltd.
% Suyeon Baek
RA Team
1F~3F, 4F(Part), 5F, 265, Daeji-Ro, Suji-gu
Yongin-si, Gyeonggi-do 16882
REPUBLIC OF KOREA

Re: K251798
Trade/Device Name: RCT700
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: July 1, 2025
Received: October 30, 2025

Dear Suyeon Baek:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251798

Device Name
RCT700

Indications for Use *(Describe)*
RCT700 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway and ENT structure for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.
The device is to be operated and used by dentists or other legally qualified heath care professionals

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

K251798

1. 510(k) Summary

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

2. Date

July 4, 2025

3. Administrative Information

Applicant		Ray Co., Ltd.
Address		1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
Manufacturer	Name	Ray Co., Ltd.
	Address	1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
	Tel	+82-31-605-1000
	Fax	+82-2-6280-5534
Contact Person	Name	Suyeon Baek
	Email	suyeon.baek@raymedical.com

4. Device Information

Trade/Proprietary Name		RCT700
Common Name		Dental Panoramic/Tomography and Cephalometric X-ray System
Classification Name	Device	Computed tomography x-ray system
	Regulation Number	21 CFR 892.1750
	Class	2
	Product Code	OAS
	Review Panel	Radiology

5. Predicate device

Parameter	Predicate Device
Device Name	RCT700
Manufacturer	Ray Co., Ltd
510(K) Number	K213226
Classification name	Computed tomography x-ray system
Regulation number	892.1750
Primary product code	OAS

6. Device Description

RCT700 provides 3D computed tomography for scanning hard tissues such as bone and teeth. By rotating the C-arm, which houses a high-voltage generator, an X-ray tube and a detector on each end, CBCT images of dental maxillofacial structures are obtained by recombining data scanned from the same level at different angles. Functionalities include panoramic image scanning for obtaining images of whole teeth, and a cephalometric option for obtaining cephalometric images.

7. Indications for Use

RCT700 is CBCT and panoramic x-ray imaging system with cephalometric.
Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway and ENT structure for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.
The device is to be operated and used by dentists or other legally qualified heath care professionals

8. Patient population

The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.
There is no restriction for ethnic group, Gender, age, weight, health, or condition.
We recommend patients for x-ray diagnostic radiation exposure to be over 5 years old.

9. Comparison with predicate device

The following table provides a summary of the technological characteristics of RCT700 compared to the predicate device.

Parameter		**Subject Device**	**Predicate Device**
Manufacturer		RAY Co., Ltd.	RAY Co., Ltd.
Device name		RCT700	RCT700
510(K) Number		Traditional 510K	K213226 (Traditional 510K)
Common Name		Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system
Indications for use		Same as predicate device	RCT700 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway and ENT structure for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment. The device is to be operated and used by dentists or other legally qualified heath care professionals
Mode of Operation		Same as predicate device	Continuous operation with intermittent, stated permissible loading
3D technology		Same as predicate device	CBCT Cone beam Computed Tomography
Performance Specification		Same as predicate device	1) CBCT Computed tomography - Patient 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type
Functional Option		Same as predicate device	Base CT+PANO Option(CEPH) CT + PANO + SCAN CEPH CT + PANO + One shot(One shot, Standard Type) CT + PANO + One shot(One shot, Large Type).
Detector Type	CT	Same as predicate device	FXDD-0606CA
		Same as predicate device	Jupi0606X1

	PANO	Same as predicate device	FXDD-0606CA
		Same as predicate device	Jupi0606X1
	Ceph (Scan)	Same as predicate device	XID-C24DC
		Pluto0900X	N/A
	Ceph (One shot)	Same as predicate device	FXDD-1012CA
		Same as predicate device	FXRD-1717VA
Exposure switch Type		Same as predicate device	“Deadman” Button type
Main Components		Same as predicate device	Ceph Apparatus
		Same as predicate device	Vertical Carriage
		Same as predicate device	Rotator
		Same as predicate device	X-RAY Generator
		Same as predicate device	X-ray tube
		Same as predicate device	High Frequency Generator
		Same as predicate device	Column
		Control panel	Touch monitor (panel)
		Detector - CT FXDD-0606CA Jupi0606X1 - PANO FXDD-0606CA Jupi0606X1 - Ceph Pluto0900X(Scan) XID-C24DC(Scan) FXDD-1012CA(One shot, Standard Size) FXRD-1717VA(One shot, Large Size)	Detector - CT FXDD-0606CA Jupi0606X1 - PANO FXDD-0606CA Jupi0606X1 - Ceph XID-C24DC(Scan) FXDD-1012CA(One shot, Standard Size) FXRD-1717VA(One shot, Large Size)
		Same as predicate device	Chinrest
		Same as predicate device	Head rest
		Same as predicate device	Automatic Collimator
		Same as predicate device	Exposure switch
		Same as predicate device	Emergency stop switch
		Same as predicate device	Console PC set
Automatic Collimator		Same as predicate device	CT exams Panoramic exams Cephalometric exams

Class		Same as predicate device	Class I with type B applied parts according to IEC 60601-1
Focal size		Same as predicate device	0.5
Field of View(CT)		Same as predicate device	Max.160x100 mm
X-ray Voltage		Same as predicate device	60~100kVp
X-ray Current		Same as predicate device	1~17mA
Total Filtration		Same as predicate device	Min. 2.8 ㎜ Al equivalent
Detector Pixel size	CT	Same as predicate device	FXDD-0606CA: 119㎛
		Same as predicate device	Jupi0606X1 : 100㎛
	PANO	Same as predicate device	FXDD-0606CA: 119㎛
		Same as predicate device	Jupi0606X1 : 100㎛
	Ceph (Scan)	Same as predicate device	XID-C24DC: 100㎛
		Pluto0900X: 100㎛	N/A
	Ceph(One shot)	Same as predicate device	FXDD-1012CA : 124㎛
		Same as predicate device	FXRD-1717VA : 140㎛
Format compatible		Same as predicate device	DICOM 3.0 Format compatible
Image Viewing Software		RayScan(version 2.5.0.0)	RayScan(version 2.4.0.0)
Image acquisition		Same as predicate device	Giga-Ethernet Network
Total Height		Same as predicate device	Max 2,296mm
Weight		Same as predicate device	1) Computed Tomography(CT) + Panoramic(PANO)=185kg(407.9lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 212.5kg (468.5lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 211kg (465.2lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 211kg (465.2lb) ± 10%
Type of installation		Same as predicate device	Wall or floor mount
Patient position		Same as predicate device	Standing / Wheelchair
Applicable Standards		Same as predicate device	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2

The product is principally just the same as in the previous 510(k) #K213226.
The table 1 provides the summary of the technological characteristics of RCT700 compared to the predicate device.
The complete of differences of the subject device to the predicate device is as follows
- Detector (Added a detector of scan ceph type)
- Software version upgrade
The software of RCT700 saves the patient and image data and offers an inquiry function, in addition, supports the image generate function intended to obtain images using the RCT700 equipment and various sensors for diagnosis. And the structure and function of the software is the same as that of the predicate device(K213226).

The 510(k) for the existing detector used in our equipment is provided below.

Modality	Manufacturer	Detector Model	Cleared	510(k) No.
CT	Iray	Jupi0606X1	No PMA	K213226
CT	Vieworks	FXDD-0606CA	No PMA	K181452
Pano	Vieworks	FXDD-0606CA	No PMA	K181452
Pano	Iray	Jupi0606X1	No PMA	K213226
Scan Ceph	i3system	XID-C24DC	No PMA	K181452
Scan Ceph	Iray	Pluto0900X	No PMA	K211159
One shot Ceph	Vieworks	FXRD-1717VA	No PMA	K181003
One shot Ceph	Vieworks	FXDD-1012CA	No PMA	K182805

10. Safety and Effectiveness Information

RCT700 system described in this 510(k) is similar to the predicate device in terms of indications for use, materials, safety characteristics, and X-ray source.
The following information further substantiates the substantial equivalence between the subject device and predicate device. The fundamental technological characteristics of the subject and predicate device are similar. The imaging modes are similar; PANO, CEPH (Optional), CBCT. The sponsor tested the subject device in a laboratory and provided a non-clinical performance report. The same test protocol was used to test the performance of the subject and the predicate device for comparison. The sponsor certifies that adequate design and development controls (according to 21 CFR 820.30) were in place for manufacturing the subject device.

The complete of differences of the subject device to the predicate device is as follows
- Detector (Added a detector of scan ceph type)
- Software version upgrade

Electrical, mechanical and environmental safety testing according to the standard of IEC 60601-1:2005/AMD1:2020 (3.2 Edition), IEC 60601-1-3:2008/AMD1:2013/AMD2:2021 (2.2 Edition), IEC 60601-1-6:2010/AMD1:2013/AMD2:2020 (3.2 Edition), and IEC 60601-2-63:2012/AMD1:2017/AMD2:2021 (1.2 Edition) were performed.
EMC testing was conducted in accordance with the standard IEC 60601-1-2:2014+AMD1:2020 (Edition 4.1).

The software of RCT700 saves patient and image data and offers an inquiry function. In addition, it supports the image generate function intended to obtain images using the RCT700 equipment and various sensors for diagnosis. That has been validated according to the FDA Guidance for the “Content of Premarket Submissions for Device Software Functions” and “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” to assure substantial equivalence. The software for this device was considered a “Basic Documentation Level” of concern since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.
As a result, we identified the level of concern associated with a new device and provided documentation consistent with that level. Based on our risk analysis of software, the difference does not affect its safety and effectiveness.

Bench testing was conducted according to FDA Guidance “Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices”. Bench testing is used to assess whether the parameters required to describe functionalities related to imaging properties of the dental X-ray device and patient dosage satisfy the designated tolerance.

Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4 and IEC 61223-3-7. All test results were satisfactory.

Non-clinical considerations were conducted in accordance with FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices". Because the subject device used the same detector as the predicate device, there is no significant difference between the two devices as a result of non-clinical testing.
Clinical considerations were conducted according to the FDA Guidance "Electronic Submission Template for Medical Device 510(k) Submissions: Guidance for Industry and Food and Drug Administration Staff," Section “Performance Testing – Clinical” Clinical

images were provided, and they provide further evidence, in addition to the laboratory performance data, to show that the complete system works as intended.

The features of RCT700 were clinically tested and approved by one licensed practitioners/clinicians. Clinical imaging samples were collected from new detectors on the proposed device at the two offices where the predicate device was installed for the clinical test images. These images were gathered from all detectors installed with RCT700 using protocols with random patient age, gender, and size. A licensed practitioner reviewed the sample clinical images and deemed them to be of acceptable quality for the intended use.

11. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Ray Co., Ltd. concludes that the new RCT700 is safe, effective and substantially equivalent to the predicate device as described herein.