March 12, 2025

RAY Co., Ltd.
℅ Soo Ji Huh
Official Correspondent
1F~3F, 4F(Part), 5F, 265, Daeji-Ro, Suji-gu
Yongin-si, Gyeonggi-do 16882
SOUTH KOREA

Re: K243903
Trade/Device Name: RCT600
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: December 19, 2024
Received: December 19, 2024

Dear Soo Ji Huh:

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 Radiological 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243903

Device Name
RCT600

Indications for Use *(Describe)*
RCT600 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus and TMJ structure for diagnostic support for adult and pediatric patients. 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary - K243903

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

December 19, 2024

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	Sooji Huh
	Email	sooji.huh@raymedical.co.kr

4. Device Information

Trade/Proprietary Name		RCT600
Common Name		Computed Tomography X-Ray System
Classification Name	Device	X-ray tomography, computed, dental
	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

RCT600 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. Indication for use

RCT600 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus and TMJ structure for diagnostic support for adult and pediatric patients. 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

8. Patient population

The patient population that may receive X-ray diagnostic radiation exposure includes individuals of any ethnic group, gender, weight, health status, or condition.

We recommend that patients who undergo X-ray diagnostic radiation exposure be over 5 years old.

9. Comparison with predicate device

The following table provides the summary of the technological characteristics of RCT600 compared to the predicate device.

Parameter		Proposed Device	Predicate Device
Manufacturer		Ray Co., Ltd.	Ray Co., Ltd.
Device name		RCT600	RCT700
510(K) Number		(Traditional 510K)	K213226 (Traditional 510K)
Common Name		Computed Tomography X-Ray System	Dental panoramic/tomography and cephalometric x-ray system
Indications for use		RCT600 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus and TMJ structure for diagnostic support for adult and pediatric patients. 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	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 health care professionals.
Mode of Operation		Same as predicate device #1	Continuous operation with intermittent, stated permissible loading
3D technology		Same as predicate device #1	CBCT Cone beam Computed Tomography
Performance Specification		1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - Scan type	1) CBCT Computed tomography - Patient 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type
Functional Option		Base CT + PANO Option(CEPH) CT + PANO + SCAN CEPH	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	CT	N/A	FXDD-0606CA

Type		Same as predicate device #1	Jupi0606X1
	PANO	N/A	FXDD-0606CA
		Same as predicate device #1	Jupi0606X1
	Ceph (Scan)	Pluto0900X	XID-C24DC
	Ceph (One shot)	N/A	FXRD-1717VA
		N/A	FXDD-1012CA
Exposure switch Type		Same as predicate device #1	“Deadman” Button type
Main Components		Same as predicate device #1	Ceph Apparatus
		Same as predicate device #1	Vertical Carriage
		Same as predicate device #1	Rotator
		Same as predicate device #1	X-RAY Generator
		Same as predicate device #1	X-ray tube
		Same as predicate device #1	High Frequency Generator
		Same as predicate device #1	Column
		Control panel	Touch monitor (panel)
		Detector -CT Jupi0606X1 -PANO Jupi0606X1 -Ceph Pluto0900X(Scan)	Detector -CT FXDD-0606CA Jupi0606X1 -PANO FXDD-0606CA Jupi0606X1 -Ceph XID-C24DC(Scan) FXRD-1717VA(One shot, Large Size) FXDD-1012CA(One shot, Standard Size)
		Same as predicate device #1	Chinrest
		Temple support	Head rest
		Same as predicate device #1	Automatic Collimator
		Same as predicate device #1	Exposure switch
		Same as predicate device #1	Emergency stop switch
		N/A	Console PC set
Automatic Collimator		Same as predicate device #1	CT exams Panoramic exams Cephalometric exams

Class		Same as predicate device #1	Class I with type B applied parts according to IEC 60601-1
Focal size		Same as predicate device #1	0.5
Field of View(CT)		Same as predicate device #1	Max. 160x100 mm
X-ray Voltage		Same as predicate device #1	60~100kVp
X-ray Current		Same as predicate device #1	1~17mA
Total Filtration		Same as predicate device #1	Min. 2.8 ㎜ Al equivalent
Detector Pixel size	CT	N/A	FXDD-0606CA: 119㎛
		Same as predicate device #1	Jupi0606X1 : 100㎛
	PANO	N/A	FXDD-0606CA: 119㎛
		Same as predicate device #1	Jupi0606X1 : 100㎛
	Ceph (Scan)	Pluto0900X: 100㎛	XID-C24DC: 100㎛
	Ceph(One shot)	N/A	FXRD-1717VA : 140㎛
		N/A	FXDD-1012CA : 124㎛
Magnification	CT	1.55	1.44
	PANO	1.44	1.31
	Ceph (Scan)	Same as predicate device #1	1.11
	Ceph(One shot)	N/A	Large Type: 1.13
		N/A	Standard Type: 1.12
Scan time		CT : below 20sec	CT : below 14sec
		Same as predicate device #1	Pano : below 14sec
		Ceph[Scan size] : below 17.6sec	Ceph[Scan size] : below 20sec
		N/A	Ceph[One shot size]: below 2 sec
Format compatible		Same as predicate device #1	DICOM 3.0 Format compatible
Image Viewing Software		SMARTScam	RayScan
Image acquisition		Same as predicate device #1	Giga-Ethernet Network
Total Height		Max 2,288mm	Max 2,296mm

Weight	1) Computed Tomography(CT) + Panoramic(PANO)=196kg(432.1lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 217kg (478.4lb) ± 10%	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 #1	Wall or floor mount
Patient position	Same as predicate device #1	Standing / Wheelchair
Applicable Standards	Same as predicate device #1	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 complete of differences of the subject device to the predicate device #K213226 is as follows

- Delete of the One-shot Ceph Option
- Detector (using Scan Ceph)
- The magnification of CT and Panorama has been changed from 1.44 and 1.31 to 1.55 and 1.44
- The CT, Scan ceph scan time has been changed from 14sec and 20sec to 20sec and 17.6sec
- Change of the Image viewing software

However, X-ray voltage, X-ray current, and CT, Pano detector was identified in #K213226.
The 510(k) for the existing detector used in our equipment is provided below.

Modality	Detector Model	Cleared	510(k) No.
CT	Jupi0606X1	No PMA	K213226
Pano	Jupi0606X1	No PMA	K213226
Scan Ceph	Pluto0900X	No PMA	K211159

10. Safety and Effectiveness Information

The RCT600 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 devices 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 predicate devices 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 differences are as follows.

- Delete of the One-shot Ceph Option
- Detector (using Scan Ceph).
- The magnification of CT and Panorama has been changed from 1.44 and 1.31 to 1.55 and 1.44
- The CT, Scan ceph scan time has been changed from 14sec and 20sec to 20sec and 17.6sec
- Change of the Image viewing software

However, X-ray voltage, X-ray current, and CT, Pano detector was identified in #K213226.

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 RCT600 saves patient and image data and offers an inquiry function. In addition, it supports the image generate function intended to obtain images using the RCT600 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 the 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 x-ray exposure parameters are adequate to generate images of diagnostic quality.

Testing for Imaging Performance was conducted according to the recognized standards IEC 61223-3-4 and IEC 61223-3-7. Key image quality performance metrics such as MTF, DQE, and NPS demonstrated that there are no significant differences between the two devices. All test results are satisfactory and they indicate safety and effectiveness for the dental system RCT600.

Non-clinical considerations were conducted in accordance with the FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices." Because the subject device uses the same detector as the predicate device, there are no significant differences between the two devices as a result of non-clinical testing.

Clinical testing was conducted according to the FDA Document "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices". Sample clinical images were submitted for each imaging dental modality, and they provide evidence to show that the RCT600 works as intended while generating images of diagnostic quality.

The features of RCT600 (including CBCT, panoramic, and cephalometric acquisitions) were clinically tested and approved by an independent, licensed practitioner/clinician DDS/ABOMR). Clinical images were gathered from all detectors of the RCT600 system using recognized protocols for image acquisition. A licensed practitioner reviewed the sample clinical images and deemed them to be of acceptable quality for the device 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 newly RCT600 is safe, effective and substantially equivalent to the predicate device as described herein.