November 29, 2021

RAY Co., Ltd
℅ Ms. Youna Im
RA Assistant Manager
332-7, Samsung 1-ro
Hwaseong-si, 18380
REPUBLIC OF KOREA

Re: K213226
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: September 27, 2021
Received: September 29, 2021

Dear Ms. Im:

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 and Part 809); 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)*

K213226

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 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.

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5. 510(K) Summary

K213226

510(k) Summary

K213226

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: September 27, 2021

3. Administrative Information

APPLICANT RAY Co.,Ltd

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Manufacturer RAY Co.,Ltd
332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 18380, Korea

TEL : +82-31-605-1000
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Contact Person e-mail : youna.im@raymedical.co.kr

4. Device Information

Device Name

Trade/Proprietary Name: RCT700
Common Name: Dental panoramic/tomography and cephalometric x-ray system

Classification

Classification Name: Computed tomography x-ray system
Regulation Number : 21 CFR 892.1750
Class : II
Product code : OAS
Panel : Radiology

5. Predicate device

Parameter	Predicate Device-1	Predicate Device-1
Device Name	RCT700	RCT800
Manufacturer	RAY Co., Ltd	RAY Co., Ltd

510(K) Number	K182614	K192737
Classification name	Computed tomography x-ray system	Computed tomography x-ray system
Regulation number	892.1750	892.1750
Primary product code	OAS	OAS

7. Device Description

System purpose RCT700 is 3D computed tomography for scanning hard tissues like bone and teeth. By rotating the c-arm which is embedded with high voltage generator all-in-one x-ray tube and a detector on each end, CBCT images of dental maxillofacial is attained by recombining data from the same level that are scanned from different angle.

Panoramic image scanning function for attaining image of whole teeth, cephalometric scanning option for attaining cephalic image, and Model Scan option for attaining dental model CBCT image are included.

8. Indication 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 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

9. 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, weight, health, or condition.
We recommend patients for x-ray diagnostic radiation exposure to be over 5 years old.

10. Comparison with predicate device

The following table provides the summary of the technological characteristics of RCT800 compared to the predicate device.

Parameter	Proposed Device	Predicate Device-1	Predicate Device-2
Manufacturer	RAY Co., Ltd.	RAY Co., Ltd.	RAY Co., Ltd.
Device name	RCT700	RCT700	RCT800
510(K) Number	(Traditional 510K)	K182614 (Special 510K)	K192737 (Traditional 510K)
Common Name	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system
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 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, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique.	RCT800 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway 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 #1	Continuous operation with intermittent, stated permissible loading	Same as predicate device #1
3D technology	Same as predicate device #1	CBCT Cone beam Computed Tomography	Same as predicate device #1

Performance Specification		Same as predicate device #1	1) CBCT Computed tomography - Patient 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type	1) CBCT Computed tomography - Patient - Dental Model Scan(Optional) 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type
Functional Option		Same as predicate device #1	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).	Same as predicate device #1
Detector Type	CT	Same as predicate device #1	FXDD-0606CA	Same as predicate device #1
		Jupi0606X	SiX 650HD-E	FXDD-1012CH
	PANO	Same as predicate device #1	FXDD-0606CA	Same as predicate device #1
		Jupi0606X	SiX 650HD-E	FXDD-1012CH
	Ceph (Scan)	Same as predicate device #1	XID-C24DC	Same as predicate device #1
	Ceph (One shot)	FXDD-1012CA	PaxScan 2530C	Same as predicate device #1
		FXRD-1717VA	1717SCC	Same as predicate device #1
Exposure switch Type		Same as predicate device #1	“Deadman” Button type	Same as predicate device #1
Main Components		Same as predicate device #1	Ceph Apparatus	Same as predicate device #1
		Same as predicate device #1	Vertical Carriage	Same as predicate device #1
		Same as predicate device #1	Rotator	Same as predicate device #1

	Same as predicate device #1	X-RAY Generator	Same as predicate device #1
	Same as predicate device #1	X-ray tube	Same as predicate device #1
	Same as predicate device #1	High Frequency Generator	Same as predicate device #1
	Same as predicate device #1	Column	Same as predicate device #1
	Same as predicate device #1	Touch monitor (panel)	Same as predicate device #1
	Detector - CT FXDD-0606CA Jupi0606X - PANO FXDD-0606CA Jupi0606X - Ceph XID-C24DC(Scan) FXDD-1012CA(One shot, Standard Size) FXRD-1717VA(One shot, Large Size)	Detector - CT FXDD-0606CA SiX 650HD-E - PANO FXDD-0606CA SiX 650HD-E - Ceph XID-C24DC(Scan) PaxScan 2530C(One shot, Standard Size) 1717SCC(One shot, Large Size)	Detector - CT FXDD-0606CA FXDD-1012CH - PANO FXDD-0606CA FXDD-1012CHA - Ceph XID-C24DC(Scan) PaxScan 2530C(One shot, Standard Size) 1717SCC(One shot, Large Size)
	Same as predicate device #1	Chinrest	Same as predicate device #1
	Same as predicate device #1	Head rest	Same as predicate device #1
	Same as predicate device #1	Automatic Collimator	Same as predicate device #1
	Same as predicate device #1	Exposure switch	Same as predicate device #1
	Same as predicate device #1	Emergency stop switch	Same as predicate device #1
	Same as predicate device #1	Console PC set	Same as predicate device #1
Automatic Collimator	Same as predicate device #1	CT exams Panoramic exams Cephalometric exams	Same as predicate device #1

Display Type		Same as predicate device #1	TFT LCD type(Normally black) *1280x800 pixel	Same as predicate device #1
Class		Same as predicate device #1	Class I with type B applied parts according to IEC 60601-1	Same as predicate device #1
Focal size		Same as predicate device #1	0.5	Patient 0.5 Model scan 0.04 (Optional)
Field of View(CT)		Same as predicate device #1	Max.160x100 mm	FXDD-0606CA : Max.160x100 mm FXDD-1012CHA : Max. 200x200 mm
X-ray Voltage(Patient)		Same as predicate device #2	60~90kVp	60~100kVp
X-ray Current(Patient)		1~17mA	4~17mA	Same as predicate device #1
Total Filtration		Same as predicate device #1	Min. 2.8 ㎜ Al equivalent	Same as predicate device #1
Detector Pixel size	CT	Same as predicate device #1	FXDD-0606CA: 119㎛	Same as predicate device #1
		Jupi0606X : 100㎛	SiX 650HD-E : 150㎛	FXDD-1012CHA: 124㎛
	PANO	Same as predicate device #1	FXDD-0606CA: 119㎛	Same as predicate device #1
		Jupi0606X : 100㎛	SiX 650HD-E : 150㎛	FXDD-1012CHA: 124㎛
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 100㎛	Same as predicate device #1
	Ceph(One shot)	FXDD-1012CA : 124㎛	PaxScan 2530C: 139㎛	Same as predicate device #1
		FXRD-1717VA : 140㎛	1717SCC: 127㎛	Same as predicate device #1
Magnification	CT	Same as predicate device #1	1.44	1.44(Patient) 1.91(Model Scan)
	PANO	Same as predicate device #1	1.31	Same as predicate device #1
	Ceph (Scan)	Same as predicate device #1	1.11	Same as predicate device #1
	Ceph(One shot)	Same as predicate device #1	Standard Size : 1.12	Same as predicate device #1
		Same as predicate device #1	Large Size : 1.13	Same as predicate device #1
Scan time		Same as predicate device #1	CT : below 14sec	CT : below 20sec

	Same as predicate device #1	Pano : below 14sec	Same as predicate device #1
	Same as predicate device #2	Ceph[Scan type] : below 19sec	Ceph[Scan type] : below 20sec
	Same as predicate device #1	Ceph[One shot type]: below 2sec	Same as predicate device #1
Format compatible	Same as predicate device #1	DICOM 3.0 Format compatible	Same as predicate device #1
Image Viewing Software	Same as predicate device #1	RayScan (Cleared under K182614)	RayScan (Cleared under K192737)
Image acquisition	Same as predicate device #1	Giga-Ethernet Network	Same as predicate device #1
Total Height	Same as predicate device #1	Max 2,296mm	Same as predicate device #1
Weight	Same as predicate device #1	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%	1) Computed Tomography(CT) + Panoramic(PANO)=189kg(416.6lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 219kg (482.8lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 217kg (478.4lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 212kg (467.3lb) ± 10%
Type of installation	Same as predicate device #1	Wall or floor mount	Same as predicate device #1
Patient position	Same as predicate device #1	Standing / Wheelchair	Same as predicate device #1
Applicable Standards	Same as predicate device #1	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2	Same as predicate device #1

The product is principally just the same as in the previous 510(k) #K182614 and K192737.
The complete of differences of the subject device to the predicate device is as follows

- The minimum X-ray Current of the tube has been changed from 4mA to 1mA.
- Added new CT, Pano, Scan Ceph and One shot Ceph detector.

11. 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 All viewing software programs have been cleared with previous 510k submissions; RAYSCAN(K182614).
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 differences are as follows.

- The minimum X-ray Current of the tube has been changed from 4mA to 1mA.
- The irradiation time of One shot Ceph has been changed.

Electrical, mechanical and environmental safety testing according to standard of
IEC 60601-1: 2005/AMD1:2012(3.1 Edition), IEC 60601-1-3: 2008/AMD1:2013(Second Edition), IEC 60601-1-6:2010(Third Edition) and IEC 60601-2-63: 2012/AMD1:2017(First Edition) were performed.
EMC testing was conducted in accordance with the standard IEC 60601-1-2: 2014(Edition 4.0).

The device software, named Rayscan, 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 that has been validated according to FDA “Guidance for the Content d Premarket Submissions for Software Contained in Medical Devices” and “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” to assure substantial equivalence.
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 All viewing software programs have been cleared with previous 510k submissions; RAYSCAN(K182614).
The software for this device was considered as a “moderate” 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 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 “Format for Traditional and Abbreviated 510(k)s.
Bench testing is used to assess whether or not the parameter measured required for describing functionalities related to imaging properties of the dental X-ray device and patient dosage satisfies the designated tolerance.
Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4 and IEC 61223-3-5.
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 FDA Guidance “Format for Traditional and Abbreviated 510(k)s.
Clinical images were provided these images were not necessary to establish substantial equivalence based on the modifications to the device but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.
The features of RCT700 have been clinically tested and approved by two licensed practitioners/ clinicians.
The clinical imaging samples are collected from the all detector on propose device at the 2 offices where the predicate device is installed on clinical consideration report for the clinical test images. These images were gathered from the all detector installed with RCT700 on any protocols with random patient age, gender, and size. A licensed practitioner reviewed the sample clinical images and found them to be of acceptable quality for the intended use.

12. 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 RCT700 is safe and effective and substantially equivalent to predicate device as described herein.