July 27, 2018

Ray Co., Ltd.
% Changhwan Lee
RA Manager
332-7, Samsung 1-ro
Hwaseong-si, Gyeonggi-do 18380
REPUBLIC OF KOREA

Re: K181452
Trade/Device Name: RCT800
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: May 27, 2017
Received: June 6, 2018

Dear Changhwan Lee:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181452

Device Name
RCT800

Indications for Use *(Describe)*

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. 510(k) Summary

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

2. Date: May 27, 2018

3. 510(k) Number K181452

4. Administrative Information

APPLICANT RAY Co.,Ltd

ADDRESS #332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 18380, Korea

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

TEL : +82-31-605-1000
FAX : +82-2-6280-5534

Contact Person e-mail : ch0406.lee@raymedical.co.kr

5. Device Information

Device Name

Trade/Proprietary Name: RCT800
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

6. Predicate device

Parameter	Predicate Device-1	Predicate Device-2
Device Name	RCT700	Green Smart (Model: PHT-65LHS)
Manufacturer	RAY Co., Ltd	Vatech Co., Ltd.

510(K) Number	K160525 Traditional 510k	K170066 Traditional 510k
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 RCT800 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

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.

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. Operating principle

The purpose of this unit is diagnose clinical structures of a tooth and head areas mainly by using the characteristics of permeability from X-ray. The principle of functioning and formations are as following. The machine is made of X-ray generator and arms in which transfers X-ray signals to a sensor in 2D. Also, an object that has a magnification is required in a distance. Moreover, the unit has to be adjustable depending on height of a patient and PC system to reconstruct an image.
The arm parts are controlled for rotating and linear moving to synchronize between the sensor and X-

ray generator to get the image of interests. The purpose of this mechanism is to provide the images in 2D or/and 3D as preferred to diagnose in a monitor. CBCT provides in 3D images as reconstructed and Panorama is to diagnose the structures in a panoramic view. Cephalometric allows for orthodontic treatment. These 3 functions could be in 1 system, Panorama with Cephalometric, or Panorama only system depending on the needs. To provide the features as mentioned above, digital transferring from permeated X-ray to absorbing to the sensor is essential and all the process are proceed in Detector. Detector transfers X-ray to light depending on the structure materials. Detector is separated into indirect method that the light is changed to digital signals on photodiode and direct method in which the light is directly transferred to digital signal. This unit is using both direct and indirect method depending on the interior structure materials.

11. Comparison with predicate device

The product is principally just the same as in the previous 510(k) #K160525.

The indications for use are expanded to include the model scan.
But, the operating principle of the model scan is the CBCT. So, Model scan is thought to be similar to previous 510(k) #K170066.

The expanded intended use of the RCT800 and the predicate device #K160525 and #K170066 is identical.

The compared technical features for imaging technology, FOV, imaging parameters, resolution, and other basic characteristics are matching very closely, and the differences are so small that they do not have any effect on performance in practice. Both devices conform to given international performance standards.

Parameter	Proposed Device	Predicate Device	Predicated Device
Manufacturer	RAY Co., Ltd.	RAY Co., Ltd.	Vatech Co., Ltd.
Device name	RCT800	RCT700	Green16/Green18
510(K) Number	K181452 (Traditional 510K)	K160525 (Traditional 510K)	K170066 (Traditional 510K)
Common Name	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system	Dental Computed Tomography X-ray System
Indications for use	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.	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.	PHT-65LHS is intended to produce panoramic, cephalometric or 3D digital x-ray images. It provides diagnostic details of the dento-maxillofacial, ENT, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.

Mode of Operation		Same as predicate device #1	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading
3D technology		Same as predicate device #1	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography
Performance Specification		1) CBCT Computed tomography - Patient - Dental Model Scan(Optional) 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type	1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type	1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - One shot 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).	Base CT+PANO Option(CEPH) CT + PANO + CEPH
Detector Type	CT	FXDD-0606CA	SiX 650HD-E	Xmaru1314CF
				Xmaru1515CF
	PANO	FXDD-0606CA	C10500D	Xmaru1314CF
			SiX 650HD-E	Xmaru1515CF
			XID-C15DP	
	Ceph (Scan)	Same as predicate device #1	XID-C24DC	
	Ceph (One shot)	1717SCC	PaxScan 4336X	
		Same as predicate device #1	PaxScan 2530C	Xmaru2602CF

Exposure switch Type	Same as predicate device #1	“Deadman” Button type	“Deadman” Button type
Main Components	Same as predicate device #1	Ceph Apparatus	Ceph Apparatus
	Same as predicate device #1	Vertical Carriage	Vertical Carriage
	Same as predicate device #1	Rotator	Rotator
	Same as predicate device #1	X-RAY Generator	X-RAY Generator
	Same as predicate device #1	X-ray tube	X-ray tube
	Same as predicate device #1	High Frequency Generator	High Frequency Generator
	Same as predicate device #1	Column	Column
	Same as predicate device #1	Touch monitor (panel)	Touch monitor (panel)
	Detector - CT FXDD-0606CA - PANO FXDD-0606CA - Ceph XID-C24DC(Scan) 1717SCC(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)	Detector - CT SiX 650HD-E - PANO C10500D SiX 650HD-E XID-C15DP - Ceph XID-C24DC(Scan) PaxScan 4336X(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)	Detector - CT Xmaru1314CF Xmaru1515CF - PANO Xmaru1314CF Xmaru1515CF - Ceph Xmaru2602CF
	Same as predicate device #1	Chinrest	Chinrest
	Same as predicate device #1	Head rest	Head rest
	Same as predicate device #1	Automatic Collimator	Unknown
	Same as predicate device #1	Exposure switch	Exposure switch
	Same as predicate device #1	Emergency stop switch	Emergency stop switch

		Same as predicate device #1	Console PC set	Console PC set
Automatic Collimator		Same as predicate device #1	CT exams Panoramic exams Cephalometric exams	Unknown
Display Type		Same as predicate device #1	TFT LCD type(Normally black) *1280x800 pixel	Unknown
Class		Same as predicate device #1	Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1
Focal size		Patient 0.5 Model scan 0.04 (Optional)	0.5	0.5
Field of View(CT)		Same as predicate device #1	Max.160x100 mm	Max. 180x100mm
X-ray Voltage(Patient)		Same as predicate device #1	60~90kVp	60~99kVp
X-ray Current(Patient)		Same as predicate device #1	4~17mA	4~16mA
X-ray Voltage(Model Scan, Optional)		50~80kVp		60~99kVp
X-ray Current(Model Scan, Optional)		0.4~0.7mA		4~16mA
Total Filtration		Min. 2.8 ㎜ Al equivalent	Min. 2.75 ㎜ Al equivalent	Min. 2.5 ㎜ Al equivalent
Detector Pixel size	CT	FXDD-0606CA: 119㎛	SiX 650HD-E: 150㎛	Xmaru1314CF: 99㎛ – 2x2 binning (detector Spec) 198㎛ – 4x4 binning (System Spec)
				Xmaru1515CF: 99㎛ – 2x2 binning (detector Spec) 198㎛ – 4x4 binning (System Spec)
	PANO	FXDD-0606CA: 119㎛	C10500D: 100㎛	Xmaru1314CF: 99㎛ – 2x2 binning (detector Spec) 198㎛ – 4x4 binning (System Spec)

			SiX 650HD-E: 150㎛	Xmaru1515CF: 99㎛ – 2x2 binning (detector Spec) 198㎛ – 4x4 binning (System Spec)
			XID-C15DP: 100㎛	
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 100㎛	
	Ceph(One shot)	1717SCC: 127㎛	PaxScan 4336X: 139㎛	
		Same as predicate device #1	PaxScan 2530C: 139㎛	Xmaru2602CF: 100㎛ - Non binning (Detector Spec) 200㎛ – 2x2 binning (System Spec)
Magnification	CT	FXDD-0606CA: 1.44(Patient) 1.91(Model Scan)	SiX 650HD-E: 1.39	Unknown
	PANO	FXDD-0606CA: 1.3	C10500D: 1.31	Unknown
			SiX 650HD-E: 1.31	Unknown
			XID-C15DP: 1.31	Unknown
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 1.11	Unknown
	Ceph(One shot)	Same as predicate device #1	PaxScan 4336X: 1.13	Unknown
		Same as predicate device #1	PaxScan 2530C: 1.12	Unknown
Scan time		CT : below 14sec(Patient) CT : below 180sec(Model Scan)	CT : below 14sec(Patient)	CT : 14sec
		Same as predicate device #1	Pano : below 14sec	Pano : 14sec
		Ceph[Scan type] : below 19sec	Ceph[Scan type] : below 18sec	Ceph[Scan type] : below 18sec
		Same as predicate device #1	Ceph[One shot type]: below 2sec	Ceph[One shot type, α-Multi3D]: 0.3sec~3.0sec
Format compatible		Same as predicate device #1	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Image Viewing Software		Same as predicate device #1	RayScan (Cleared under K160525)	Ezdent-i (K161117)

Image acquisition	Same as predicate device #1	Giga-Ethernet Network	Giga-Ethernet Network
Total Height	Same as predicate device #1	Max 2,296mm	Max 2,304mm
Weight	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%	1) Computed Tomography(CT) + Panoramic(PANO)=150kg(331lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 166kg (366lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 166kg (366lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 166kg (366lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO)=187kg(412.3lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph 212kg (467.4lb) ± 10%
Type of installation	Same as predicate device #1	Wall or floor mount	Wall or floor mount
Patient position	Same as predicate device #1	Standing / Wheelchair	Standing / Wheelchair
Applicable Standards	Same as predicate device #2	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-63 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2

12. Safety and Effectiveness Information

RCT800 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, Model Scan All viewing software programs have been cleared with previous 510k submissions; RAYSCAN(K160525).
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 subject device is equipped with new detectors, FXDD-0606CA, 1717SCC. And new High Voltage Generator, X-ray Tube for Model Scan.

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(first Edition) were performed.
EMC testing was conducted in accordance with the standard IEC 60601-1-2: 2014(Edition 4.0).

The software of RCT800 saves the patient and image data and offers an inquiry function, in addition, supports the image generate function intended to obtain images using the RCT800 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.
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, section 18, Performance Testing – Bench”
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".
RCT800 is equipped with FXDD-0606CA. FXDD-0606CA is a new SSXI detector, which is used to capture an image in panoramic, CBCT and Model Scan mode.
Based on Non-Clinical Test results of FXDD-0606CA for the subject device, is similar to that of the SiX 650HD-E for the Predicate device. And equipped with 1717SCC is a new SSXI detector, which is used to capture an image in Cephalometric. Based on Non-Clinical Test results of 1717SCC for the subject device, is similar to that of the PaxScan 4336X for the Predicate device.
All test results were satisfactory.

Clinical considerations were conducted according to FDA Guidance “Format for Traditional and Abbreviated 510(k)s, section 20”.
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.
For clinical testing, two licensed practitioners/clinicians observed and verified that dental X ray system from RCT800.
The clinical imaging samples are collected from the new 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 new detector installed with RCT800 on any protocols with random patient age, gender, and size. As licensed practitioners or clinician diagnoses of the images, it might be proved that the clinical diagnosis and structures are acceptable in the region of interests.

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 RCT800 is safe and effective and substantially equivalent to predicate device as described herein.