December 14, 2018

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

Re: K182805
Trade/Device Name: RCT800
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: September 27, 2018
Received: October 2, 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. 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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 A. 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)*
K182805

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.

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5. 510(K) Summary

510(k) Summary

1. 510(k) Summary - K182805

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: September 27, 2018

3. Administrative Information

APPLICANT RAY Co.,Ltd

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TEL : +82-31-605-1000
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4. 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

5. Predicate device

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

510(K) Number	K181452 Traditional 510k
Classification name	Computed tomography x-ray system
Regulation number	892.1750
Primary product code	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) #K181452.
We added a CT/Pano detector to the predicate Device #K181452.
And, CT protocol and FOV size have changed slightly due to the added detector.

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
Manufacturer	RAY Co., Ltd.	RAY Co., Ltd.
Device name	RCT800	RCT800
510(K) Number	(Special 510K)	K181452 (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 #1	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
3D technology	Same as predicate device #1	CBCT Cone beam Computed Tomography
Performance Specification	Same as predicate device #1	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).

Detector Type	CT	Same as predicate device #1	FXDD-0606CA
		FXDD-1012CHA	N/A
	PANO	Same as predicate device #1	FXDD-0606CA
		FXDD-1012CHA	N/A
	Ceph (Scan)	Same as predicate device #1	XID-C24DC
	Ceph (One shot)	Same as predicate device #1	1717SCC
		Same as predicate device #1	PaxScan 2530C
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
		Same as predicate device #1	Touch monitor (panel)
		Detector - CT FXDD-0606CA FXDD-1012CHA - PANO FXDD-0606CA FXDD-1012CHA - Ceph XID-C24DC(Scan) 1717SCC(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)	Detector - CT FXDD-0606CA - PANO FXDD-0606CA - Ceph XID-C24DC(Scan) 1717SCC(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)
		Same as predicate device #1	Chinrest
		Same as predicate device #1	Head rest
		Same as predicate device #1	Automatic Collimator
		Same as predicate device #1	Exposure switch
		Same as predicate device #1	Emergency stop switch
		Same as predicate device #1	Console PC set
Automatic Collimator		Same as predicate device #1	CT exams Panoramic exams Cephalometric exams

Display Type		Same as predicate device #1	TFT LCD type(Normally black) *1280x800 pixel
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	Patient 0.5 Model scan 0.04 (Optional)
Field of View(CT)		FXDD-0606CA : Max.160x100 mm FXDD-1012CHA : Max. 200x200 mm	FXDD-0606CA : Max.160x100 mm
X-ray Voltage(Patient)		Same as predicate device #1	60~90kVp
X-ray Current(Patient)		Same as predicate device #1	4~17mA
X-ray Voltage(Model Scan, Optional)		Same as predicate device #1	50~80kVp
X-ray Current(Model Scan, Optional)		Same as predicate device #1	0.4~0.7mA
Total Filtration		Same as predicate device #1	Min. 2.8 ㎜ Al equivalent
Detector Pixel size	CT	Same as predicate device #1	FXDD-0606CA: 119㎛
		FXDD-1012CHA: 124㎛	N/A
	PANO	Same as predicate device #1	FXDD-0606CA: 119㎛
		FXDD-1012CHA: 124㎛	N/A
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 100㎛
	Ceph(One shot)	Same as predicate device #1	1717SCC: 127㎛
		Same as predicate device #1	PaxScan 2530C: 139㎛
Magnification	CT	Same as predicate device #1	FXDD-0606CA: 1.44(Patient) 1.91(Model Scan)
		FXDD-1012CHA: 1.44(Patient) 1.91(Model Scan)	N/A
	PANO	Same as predicate device #1	FXDD-0606CA: 1.3
		FXDD-1012CHA: 1.3	N/A
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 1.11
	Ceph(One shot)	Same as predicate device #1	1717SCC: 1.13
		Same as predicate device #1	PaxScan 2530C: 1.12
Scan time		Same as predicate device #1	CT : below 14sec(Patient) CT : below 180sec(Model Scan)
		Same as predicate device #1	Pano : below 14sec
		Same as predicate device #1	Ceph[Scan type] : below 19sec
		Same as predicate device #1	Ceph[One shot type]: below 2sec
Format compatible		Same as predicate device #1	DICOM 3.0 Format compatible
Image Viewing Software		Same as predicate device #1	RayScan (Cleared under K181452)
Image acquisition		Same as predicate device #1	Giga-Ethernet Network
Total Height		Same as predicate device #1	Max 2,296mm

Weight	Same as predicate device #1	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
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

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(K181452).
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 CT/PANO detectors, FXDD-1012CHA.

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-1012CHA. FXDD-1012CHA 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-1012CHA for the subject device, is similar to that of the FXDD-0606CA 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.