



Food and Drug Administration
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June 20, 2016

RAY Co., Ltd.
c/o Jeff Rongero, Staff Engineer
UL LLC
12 LABORATORY DRIVE
RESEARCH TRIANGLE PARK, NC 27709

Re: K160525

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: May 6, 2016
Received: May 10, 2016

Dear Jeff Rongero:

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); labeling (21 CFR Part 801); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known)

K160525

Device Name

RCT700

Indications for Use (Describe)

CBCT, panoramic x-ray imaging system with cephalostat, is an extra oral 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 dental maxillofacial 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 Image is obtained using the standard narrow beam technique.

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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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.

Date: December 30, 2015

APPLICANT RAY Co.,Ltd

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Device Name

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

Classification

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

Predicate device

Parameter	Predicated Device-1	Predicated Device-2
Device Name	RAYSCAN α-Expert3D	RAYSCAN α-Expert3D
Manufacturer	RAY Co., Ltd	RAY Co., Ltd

510(K) Number	K122981 Traditional 510k	K142247 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

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, and cephalometric scanning option for attaining cephalometric image are included. RCT700 options combination are as shown in the table below.

Indication for use

CBCT, panoramic x-ray imaging system with cephalostat, is an extra oral 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 dental maxillofacial 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 Image is obtained using the standard narrow beam technique

“CAUTION: Federal law restricts this device to sale by or on the order of a dentist.”

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.

Device functions

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.

Operating principle of the detector

X-ray data entered into the detector from an outside source is converted to visible ray by detector's Scintillator and the visible ray is transferred to CMOS ASIC and converted to an Electric signal to form an image signal.

Then the signal is changed to a Digital form and through the high speed LAN cable, the acquired image data is transmitted to the PC.

Acquired resulting image is displayed on the monitor by the PC Software.

Detector Options

RCT700 detector, depending on the modality, consists of SIX 650HD-E (Manufacturer: THALES) in case of the CT and one of three detectors in case of PANO, C10500D-43 (Manufacturer: Hamamatsu), XID-C15DP (Manufacturer: i3System) or SIX 650HD-E (Manufacturer: THALES).

Ceph is categorized by Scan Ceph or One shot Ceph according to the imaging methodology and the detector implemented in RCT700 Scan ceph is the XID-C24DS (Manufacturer: i3system) model whereas the detector used in the One shot Ceph is PaxScan 4336X (Manufacturer: Varian medical systems) and PaxScan 2530C (Manufacturer: Varian medical systems).

In particular, the detector used in SIX 650HD-E may also be used as a detector for PANO.

Meaning the SIX 650HD-E detector is capable of being used as an independent detector in CT or the PANO modality or in CT and PANO Modality simultaneously.

RCT700 options combinations are as shown in the table below.

Device Designation		
	Division	Description
RCT700	CT + Pano	CT(SIX 650HD-E) + Pano(C10500D-43)
		CT(SIX 650HD-E) + Pano(XID-C15DP)
	CT + Pano + Scan Ceph	CT(SIX 650HD-E) + Pano(C10500D-43) + Scan Ceph(XID-C24DS)
		CT(SIX 650HD-E) + Pano(XID-C15DP) + Scan Ceph(XID-C24DS)
	CT + Pano + One shot Ceph(L)	CT(SIX 650HD-E) + Pano(C10500D-43) + One shot Ceph(PaxScan 4336X)
		CT(SIX 650HD-E) + Pano(XID-C15DP) + One shot Ceph(PaxScan 4336X)
	CT + Pano + One shot Ceph(S)	CT(SIX 650HD-E) + Pano(C10500D-43) + One shot Ceph(PaxScan 2530C)
		CT(SIX 650HD-E) + Pano(XID-C15DP) + One shot Ceph(PaxScan 2530C)
	CT	CT(SIX 650HD-E)
	CT + Scan Ceph	CT(SIX 650HD-E) + Scan Ceph(XID-C24DS)
	CT + One shot Ceph(L)	CT(SIX 650HD-E) + One shot Ceph(PaxScan 4336X)
	CT + One shot Ceph(S)	CT(SIX 650HD-E) + One shot Ceph(PaxScan 2530C)
	CT,Pano	CT,Pano(SIX 650HD-E)
	CT,Pano + Scan Ceph	CT,Pano(SIX 650HD-E) + Scan Ceph(XID-C24DS)
	CT,Pano + One shot Ceph(L)	CT,Pano(SIX 650HD-E) + One shot Ceph(PaxScan 4336X)
CT,Pano + One shot Ceph(S)	CT,Pano(SIX 650HD-E) + One shot Ceph(PaxScan 2530C)	
Remark		
*Pano: C10500D-43(Hamamatsu)		
*Pano: XID-C15DP(i3System)		
*CT: SIX 650HD-E(THALES)		
*Scan Ceph: XID-C24DS(i3system)		
*One shot Ceph(S): PaxScan 2530C(Varian medical systems)		
*One shot Ceph(L): PaxScan 4336X(Varian medical systems)		

Comparison with predicate device

Similarities:

The proposed device has the same intended for use and technical characteristic as the predicate device. A comparative analysis indicates that the following categories are similar: the mode of operation, 3D technology, performance specification, main features [such as X-ray tube, High voltage generator, CT detector, PANO detector and CEPH (Scan type, one-shot type) detector], Collimator operation type (Auto),

Class I with type B applied parts according to IEC 60601-1, focal size, DICOM 3.0 format compatible, network method, type of installation, and applicable standards. (See Table 1 for compares the characteristics between the predicate device)

Differences:

In case of RCT700, detector implemented in the device varies according to its modality; CT, PANO, Ceph and the corresponding detectors are described below.

In case of CT, Predicate devices RAYSCAN α -Expert 3D[K122981, Traditional] and RAYSCAN α -Expert3D[K142247, Traditional] included the C10900D model, however the Proposed device RCT700 includes the SIX 650HD-E model detector.

In case of PANO, Predicate devices RAYSCAN α -Expert 3D[K122981, Traditional] and RAYSCAN α -Expert3D[K142247, Traditional] uses the C10500D model whereas the Proposed device RCT700 is capable of incorporating one of 3 types of detector models; C10500D, SIX 650HD-E or XID-C15DP.

Cephalometry is classified into Scan type or the One shot type depending on the imaging method and in case of the Scan type, Predicate device included the XID-C24DS detector which is an equivalent model to that of RAYSCAN α -Expert3D[K142247, Traditional].

In the One shot type, Predicate devices RAYSCAN α -Expert 3D[K122981, Traditional] included the SDX-4336CP model detector whereas RAYSCAN α -Expert3D[K142247, Traditional] and the Proposed device is capable of handling both the PaxScan 4336X and PaxScan 2530C detector models.

These 2 types of detectors are identical in technical characteristics, method and manufacturer and the only mentionable difference is that PaxScan 4336X detector is 42.4 (V) cm x 35.3 (H) cm in size and PaxScan 2530C detector is 24.9(V)cm x 30.2(H)cm.

Hereafter, the PaxScan 4336X mounted in the proposed device RCT700 One shot type will be referred to as Large size and PaxScan 2530C detector as the standard size.

Following is the comparison table listing the type of modality detectors mounted in Predicate devices RAYSCAN α -Expert 3D[K122981, Traditional] and RAYSCAN α -Expert3D[K142247, Traditional] and the optional detector types mounted in the proposed device RCT700.

Division		Proposed Device	Predicate Device #1	Predicate Device #2
		RCT700	RAYSCAN α -Expert3D	RAYSCAN α -Expert3D
		K160525, Traditional	K122981, Traditional	K142247, Traditional
CT	Manufacturer	Thales	Hamamatsu	Same as predicate device #1
	Model	SIX 650HD-E	C10900D	
	Scintillator Material	CsI (Indirect type)	CsI (Indirect type)	
	Total pixel area	144.0(W)x117.9(H)mm	124.8(W)x124.8(H)mm	
	Total pixel	960x786	624x624	
	Pixel size	150um	200um	

	Limiting resolution	3.3lp/mm	2.5lp/mm	
	Power supply/Main	5VDC / 7.5W	5VDC / 1250mA	
	MTF	60% at 1LP/mm	58% at 1LP/mm	
	DQE	0.45 at 1LP/mm	0.22 at 1LP/mm	
	VOXEL	0.07~0.4mm	0.28mm	
PANO-1	Manufacturer	Same as predicate device #1	Hamamatsu	Same as predicate device #1
	Model		C10500D	
	Scintillator Material		CsI (Indirect type)	
	Total pixel area		6.0(W)x1512(H)mm	
	Total pixel		60x1512	
	Pixel size		100um	
	Limiting resolution		5.0lp/mm	
	Power supply/Main		5VDC / 1100mA	
	MTF		70% at 1LP/mm	
	DQE		0.5 at 1LP/mm	
PANO-2	Manufacturer	Thales	N/A	N/A
	Model	SiX 650HD-E		
	Scintillator Material	CsI (Indirect type)		
	Total pixel area	144.0(W)x117.9(H)mm		
	Total pixel	960x786		
	Pixel size	150um		
	Limiting resolution	3.3lp/mm		
	Power supply/Main	5VDC / 7.5W		
	MTF	60% at 1LP/mm		
	DQE	0.45 at 1LP/mm		
PANO-3	Manufacturer	i3System	N/A	N/A
	Model	XID-C15DP		
	Scintillator Material	CdTe(Direct type)		
	Total pixel area	4.8(W)x150(H)mm		
	Total pixel	48x1500		
	Pixel size	100um		

	Limiting resolution	5.0lp/mm		
	Power supply/Main	5VDC / 2A		
	MTF	75% at 1LP/mm		
	DQE	0.88 at 1LP/mm		
Ceph (scan type)	Manufacturer	Same as predicate device #2	N/A	i3System
	Model			XID-C24DS
	Scintillator Material			CdTe (Direct type)
	Total pixel area			4.8(W)x240(H)mm
	Total pixel			48x2400
	Pixel size			100um
	Limiting resolution			5.0lp/mm
	Power supply/Main			5VDC / 2A
	MTF			75% at 1LP/mm
	DQE			0.88 at 1LP/mm
Ceph (One shot)-1, Large Size	Manufacturer	Same as predicate device #2	Samsung Mobile Display	Varian
	Model		SDX-4336CP	PaxScan 4336X
	Scintillator Material		SDX-4336CP	GADOX (Indirect type)
	Total pixel area		43.2 x 36.0 cm	427(W)x356(H)mm
	Total pixel		2880 x 2400	3072x2560
	Pixel size		150 um	139um
	Limiting resolution		3.3 lp/mm	3.6lp/mm
	Power supply/Main		100-240VAC, 50/60Hz	100-240VAC, 47-63Hz
	MTF		45% at 1LP/mm	54% at 1LP/mm
	DQE		0.41 at 1P/mm	0.2 at 1LP/mm
Ceph (One shot)-2, Standard Size	Manufacturer	Same as predicate device #2	N/A	Varian
	Model			PaxScan 2530C
	Scintillator Material			GADOX (Indirect type)
	Total pixel area			302(W)x249(H)mm
	Total pixel			2176x1792
	Pixel size			139um
	Limiting resolution			3.6lp/mm

510(k) Submission- RCT700

	Power supply/Main			100-240VAC, 47-63Hz
	MTF			54% at 1LP/mm
	DQE			0.2 at 1LP/mm

Information for detector own 510(k) number or system in which it was cleared 510(k) number.

Division	Model	Manufacturer	Own 510(K) number	System in which it was cleared 510(k) number.
CT	SiX 650HD-E	Thales	No	1) System name: Unknown 2) Manufacturer: Unknown 3) 510(K) Number: Unknown
Pano-1	C10500D	Hamamatsu	No	1) System name: RAYSCAN α-Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K122981
Pano-2	SiX 650HD-E	Thales	No	1) System name: Unknown 2) Manufacturer: Unknown 3) 510(K) Number: Unknown
Pano-3	XID-C15DP	i3System	No	1) System name: PAPAYA plus 2) Manufacturer: Genoray 3) 510(K) Number: K130419
Scan Ceph	XID-C24DS	i3System	No	1) System name: RAYSCAN α-Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K131695
One shot Ceph	PaxScan 4336X	Varian	No	1) System name: RAYSCAN α-Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K142247
One shot Ceph	PaxScan 2530C	Varian	No	1) System name: RAYSCAN α-Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K142247

Statement of Substantial Equivalence

Parameter	Proposed Device	Predicated Device	Predicated Device
Manufacturer	RAY Co., Ltd.	RAY Co., Ltd.	RAY Co., Ltd.
Device name	RCT700	RAYSCAN α -Expert3D	RAYSCAN α -Expert3D
510(K) Number	K160525 (Traditional 510K)	K122981 (Traditional 510K)	K142247 (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	<p>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.</p> <p>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.</p>	<p>RAYSCAN α-Expert 3D, 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.</p> <p>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.</p>	<p>RAYSCAN α-Expert 3D 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.</p> <p>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.</p>
Mode of Operation	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading
3D technology	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography

Performance Specification		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	1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type
Functional Option		Refer to Device Designation table in description section of 510K summary.	Base RAYSCAN α-3D : CT+PANO Option(CEPH) RAYSCAN α-Multi 3D: CT + PANO + One shot	Base RAYSCAN α-3D : CT+PANO Option(CEPH) RAYSCAN α-SM3D: CT + PANO + SCAN CEPH RAYSCAN α-M3DS: CT + PANO + One shot(9.8 X 11.9 inch) RAYSCAN α-M3DL: CT + PANO + One shot(16.8 X 14.0 inch)
Exam Mode	CT	Jaw(Standard) Jaw-Fast Surgical guide Facial Teeth Endodontics TMJ Sinus Airway	Standard Surgical guide Implant surgery Endo treatment TMJ Sinus	Jaw(Standard) Surgical guide Implant surgery Endo treatment TMJ Sinus
	PANO	Standard(Normal) TMJ Sinus Segmentation (Individual Tooth) Bitewing Orthogonal	Normal(Adult) Pedodontics(Children) TMJ Sinus	Standard(Normal) TMJ Sinus Segmentation (Individual Tooth) Bitewing Orthogonal

	Ceph (Optional)	Posterior/Anterior Lateral SMV Carpus Reverse Town's Waters Lateral wide	PA,AP Lateral SMV Carpus Reverse Town's Waters	Posterior/Anterior Lateral SMV Carpus Reverse Town's Waters Lateral wide
Detector Type	CT	SiX 650HD-E	C10900D	C10900D
	PANO	C10500D	C10500D	C10500D
		SiX 650HD-E		
		XID-C15DP		
	Ceph (Scan)	XID-C24DS		XID-C24DS
	Ceph (One shot)	PaxScan 4336X	SDX-4336CP	PaxScan 4336X
PaxScan 2530C			PaxScan 2530C	
Exposure switch Type		"Deadman" Button type	Deadman" Button type	"Deadman" Button type
Main Components		Ceph Apparatus	Ceph Apparatus	Ceph Apparatus
		Vertical Carriage	Vertical Carriage	Vertical Carriage
		Rotator	Rotator	Rotator
		X-RAY Generator	X-RAY Generator	X-RAY Generator
		X-ray tube	X-ray tube	X-ray tube
		High Frequency Generator	High Frequency Generator	High Frequency Generator
		Column	Column	Column

	Touch monitor (panel)	Touch monitor (panel)	Touch monitor (panel)
	Detector - CT SiX 650HD-E - PANO C10500D SiX 650HD-E XID-C15DP - Ceph XID-C24DS(Scan) PaxScan 4336X(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)	Detector - CT C10900D - PANO C10500D - Ceph SDX-4336CP (One shot)	Detector - CT C10900D - PANO C10500D - Ceph XID-C24DS(Scan) PaxScan 4336X(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)
	Chinrest	Chinrest	Chinrest
	Head rest	Head rest	Head rest
	Automatic Collimator	Automatic Collimator	Automatic Collimator
	Exposure switch	Exposure switch	Exposure switch
	Emergency stop switch	Emergency stop switch	Emergency stop switch
	Console PC set	Console PC set	Console PC set
Automatic Collimator	CT exams Panoramic exams Cephalometric exams	CT exams Panoramic exams Cephalometric exams	CT exams Panoramic exams Cephalometric exams
Display Type	TFT LCD type(Normally black) *1280x800 pixel	TFT LCD type(Normally black) *1280x800 pixel	TFT LCD type(Normally black) *1280x800 pixel
Class	Class I with type B applied parts according to IEC 60601-1	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	0.5	0.5	0.5

Field of View(CT)		160x100mm (Max.)	90x90mm	90x90mm
X-ray Voltage		60~90kVp	60~90kVp	60~90kVp
X-ray Current		4~17mA	4~17mA	4~17mA
Total Filtration		2.75 mm Al equivalent	2.6 mm Al equivalent	2.6 mm Al equivalent
Detector Pixel size	CT	SiX 650HD-E: 150 μ m	C10900D: 200 μ m	C10900D: 200 μ m
	PANO	C10500D: 100 μ m	C10500D: 100 μ m	C10500D: 100 μ m
		SiX 650HD-E: 150 μ m		
		XID-C15DP: 100 μ m		
	Ceph (Scan)	XID-C24DS: 100 μ m		XID-C24DS: 100 μ m
	Ceph(One shot)	PaxScan 4336X: 139 μ m	SDX-4336CP: 150 μ m	PaxScan 4336X: 139 μ m
PaxScan 2530C: 139 μ m			PaxScan 2530C: 139 μ m	
Magnification	CT	SiX 650HD-E: 1.39	C10900D: 1.39	C10900D: 1.39
	PANO	C10500D: 1.31	C10500D: 1.31	C10500D: 1.31
		SiX 650HD-E: 1.31		
		XID-C15DP: 1.31		
	Ceph (Scan)	XID-C24DS: 1.11		XID-C24DS: 1.11
	Ceph(One shot)	PaxScan 4336X: 1.13	SDX-4336CP: 1.13	SDX-4336CP: 1.13
PaxScan 2530C: 1.12				
Scan time		CT : below 14sec	CT : 14sec	CT : 14sec
		Pano : below 14sec	Pano : 14sec	Pano : 14sec

	Ceph[Scan type] : below 18sec		Ceph[Scan type] : below 18sec
	Ceph[One shot type]: below 2sec	Ceph[One shot type, α-Multi3D]: 0.3sec~3.0sec	Ceph[One shot type, α-Multi3D]: 0.3sec~3.0sec
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Image Viewing Software	RayScan	RayScan	RayScan
Image acquisition	Giga-Ethernet Network	Giga-Ethernet Network	Giga-Ethernet Network
Total Height	Max 2,296mm	Max 2,296mm	Max 2,296mm
Weight	<p>1) Computed Tomography(CT) + Panoramic(PANO)=150kg(331lb) ± 10%</p> <p>2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 166kg (366lb) ± 10%</p> <p>3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 166kg (366lb) ± 10%</p> <p>4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 166kg (366lb) ± 10%</p>	<p>1) Computed Tomography(CT) + Panoramic(PANO)=148kg(326lb) ± 10%</p> <p>2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type)=165kg(364lb) ± 10% rlwhs</p>	<p>1) Computed Tomography(CT) + Panoramic(PANO)=148kg(326lb) ± 10%</p> <p>2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)=164kg (362lb) ± 10%</p> <p>3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type)=165kg(364lb) ± 10%</p>
Type of installation	Wall or floor mount	Wall or floor mount	Wall or floor mount
Patient position	Standing / Wheelchair	Standing / Wheelchair	Standing / Wheelchair

Applicable Standards	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-63 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-2-44 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-63 IEC 60601-1-2
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Safety and Effectiveness Information

Electrical, mechanical and environmental safety testing according to standard of IEC 60601-1: 2005 + CORR.1(2006) + CORR.2(2007), IEC 60601-1-3: 2008(Second Edition), IEC 60601-2-28: 2010(Second Edition) and IEC 60601-2-63: 2012(first Edition) were performed. EMC testing was conducted in accordance with the standard IEC 60601-1-2: 2007(Edition 3.0).

The software of RCT700 has been validated according to FDA "Guidance for the Content d Premarket Submissions for Software Contained in Medical Devices" and applicable requirements contained in the guidance document.

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".

All test results were satisfactory.

Both of the predicate device and proposed devices were test and measured by IEC 62220-1.

RCT700 system's new sensor and compared with the predicate device with regard to Modulation Transfer Function (MTF) and Device Quantum Efficiency (DQE) and Noise to power spectrums (NPS).

Based on Non-Clinical Test results of the new detector SiX-650HD-E of the subject device, the measured pixel sizes of the new sensor (SiX-650HD-E) are similar to that of the predicate device (C10900D). Therefore, compared to the predicate device, the test patterns of the new sensor images show the test subjects without aliasing phenomenon throughout the same spatial frequency as the predicate device. Moreover, the new SiX-650HD-E sensor has performed similarly or better than the predicate device in terms of the overall NPS performance, give the NPS variation in low frequency (~0.6 lp/mm). The new sensor also exhibits consistently better performances in terms of MTF.

For the new detector XID-C15DP of RCT700, the Non-Clinical test results demonstrated the similar characteristics in terms of MTF, NPS, and DQE performance compared to C10500D detector of the subject and predicate device. All performance parameter for both detectors have shown similar results.

In conclusion, the diagnostic image quality of the new sensor is equal or better than those of the predicate device and there is no significant in efficiency and safety.

RCT710 complies with FDA standards such as 21 CFR 1202.30 and 21 CFR 1020.31 and CFR 1020.33.

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 RCT700.

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 RCT700 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.

Conclusions

The proposed device and the predicate device have the same indications for use and demonstrate the similar technical characteristics. As demonstrated in the non-clinical considerations and bench test, the RCT700 performed similar the predicate device in various performance parameters such as DQE, MTF and NPS. The electrical requirement of the new device is evaluated and mitigated in electrical safety test, EMC test. Quality assurance procedures are adhered to, and meeting the specifications and functional requirements is demonstrated via testing.

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