



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

October 16, 2018

Re: K182614  
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 19, 2018  
Received: September 21, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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**

## Indications for Use

510(k) Number (if known)

K182614

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.

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  
[PRASaff@fda.hhs.gov](mailto:PRASaff@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."*

## **5. 510(K) Summary**

## 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:** August 29, 2018

### 3. 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

### 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     | Predicated Device-1         | Predicated Device-2         |
|---------------|-----------------------------|-----------------------------|
| Device Name   | RCT700                      | RCT800                      |
| Manufacturer  | RAY Co., Ltd                | RAY Co., Ltd                |
| 510(K) Number | K160525<br>Traditional 510k | K181452<br>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                              |

## 6. 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.

## 7. 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."

## 8. 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.

## 9. 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.

## 10. Comparison with predicate device

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

We changed a some scan protocol from the Predicate Device(K160525).

And added a CT/Pano and ceph detector to the predicate Device #K160525. But, these detectors is used predicate Device #K181452.

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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | RAY CO., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Device name         | RCT700                                                     | RCT700                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | RCT800                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 510(K) Number       | (Special 510K)                                             | K160525<br>(Traditional 510K)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | K181452<br>(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 | Same as predicate device #1                                | 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<br>2) Panoramic<br>3) Cephalometric(optional)<br>- One shot type<br>- Scan type                                                          | 1) CBCT Computed tomography<br>- Patient<br>- Dental Model Scan(Optional)<br>2) Panoramic<br>3) Cephalometric(optional)<br>- One shot type<br>- Scan type |
| Functional Option         |                 | Same as predicate device #1 | Base<br>CT+PANO<br><br>Option(CEPH)<br>CT + PANO + SCAN CEPH<br><br>CT + PANO + One shot(One shot, Standard Type)<br><br>CT + PANO + One shot(One shot, Large Type). | Same as predicate device #1                                                                                                                               |
| Detector Type             | CT              | Same as predicate device #1 | SiX 650HD-E                                                                                                                                                          | N/A                                                                                                                                                       |
|                           |                 | Same as predicate device #2 | N/A                                                                                                                                                                  | FXDD-0606CA                                                                                                                                               |
|                           | PANO            | Same as predicate device #1 | C10500D                                                                                                                                                              | N/A                                                                                                                                                       |
|                           |                 | Same as predicate device #1 | SiX 650HD-E                                                                                                                                                          | N/A                                                                                                                                                       |
|                           |                 | Same as predicate device #1 | XID-C15DP                                                                                                                                                            | N/A                                                                                                                                                       |
|                           |                 | Same as predicate device #2 | N/A                                                                                                                                                                  | FXDD-0606CA                                                                                                                                               |
|                           | Ceph (Scan)     | Same as predicate device #1 | XID-C24DC                                                                                                                                                            | Same as predicate device #1                                                                                                                               |
|                           | Ceph (One shot) | Same as predicate device #1 | PaxScan 4336X                                                                                                                                                        | N/A                                                                                                                                                       |

|                      |  |                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                        |                                                                                                                                                                          |
|----------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      |  | Same as predicate device #2                                                                                                                                                                                                                                           | N/A                                                                                                                                                                                                    | 1717SCC                                                                                                                                                                  |
|                      |  | Same as predicate device #1                                                                                                                                                                                                                                           | PaxScan 2530C                                                                                                                                                                                          | 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<br>- CT<br>SiX 650HD-E<br>FXDD-0606CA<br><br>- PANO<br>C10500D<br>SiX 650HD-E<br>XID-C15DP<br>FXDD-0606CA<br><br>- Ceph<br>XID-C24DC(Scan)<br>PaxScan 4336X(One shot, Large Size)<br>1717SCC(One shot, Large Size)<br>PaxScan 2530C(One shot, Standard Size) | Detector<br>- CT<br>SiX 650HD-E<br><br>- PANO<br>C10500D<br>SiX 650HD-E<br>XID-C15DP<br><br>- Ceph<br>XID-C24DC(Scan)<br>PaxScan 4336X(One shot, Large Size)<br>PaxScan 2530C(One shot, Standard Size) | Detector<br>- CT<br>FXDD-0606CA<br><br>- PANO<br>FXDD-0606CA<br><br>- Ceph<br>XID-C24DC(Scan)<br>1717SCC(One shot, Large Size)<br>PaxScan 2530C(One shot, Standard Size) |
|                      |  | 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<br>Panoramic exams<br>Cephalometric exams            | Same as predicate device #1               |
| Display Type           |      | Same as predicate device #1 | TFT LCD type(Normally black)<br>*1280x800 pixel               | Same as predicate device #1               |
| Class                  |      | Same as predicate device #1 | Class I with type B applied parts<br>according to IEC 60601-1 | Same as predicate device #1               |
| Focal size             |      | Same as predicate device #1 | 0.5                                                           | Patient 0.5<br>Model scan 0.04 (Optional) |
| Field of View(CT)      |      | Same as predicate device #1 | Max.160x100 mm                                                | Same as predicate device #1               |
| X-ray Voltage(Patient) |      | Same as predicate device #1 | 60~90kVp                                                      | Same as predicate device #1               |
| X-ray Current(Patient) |      | Same as predicate device #1 | 4~17mA                                                        | Same as predicate device #1               |
| Total Filtration       |      | Same as predicate device #2 | Min. 2.75 mm Al equivalent                                    | Min. 2.8 mm Al equivalent                 |
| Detector Pixel size    | CT   | Same as predicate device #1 | SiX 650HD-E: 150 $\mu$ m                                      |                                           |
|                        |      | Same as predicate device #2 |                                                               | FXDD-0606CA: 119 $\mu$ m                  |
|                        | PANO | Same as predicate device #1 | C10500D: 100 $\mu$ m                                          | N/A                                       |
|                        |      | Same as predicate device #1 | SiX 650HD-E: 150 $\mu$ m                                      | N/A                                       |
|                        |      | Same as predicate device #1 | XID-C15DP: 100 $\mu$ m                                        | N/A                                       |
|                        |      | Same as predicate device #2 | N/A                                                           | FXDD-0606CA: 119 $\mu$ m                  |

|                        |                |                                         |                                    |                                    |
|------------------------|----------------|-----------------------------------------|------------------------------------|------------------------------------|
|                        | Ceph (Scan)    | Same as predicate device #1             | XID-C24DC: 100μm                   | Same as predicate device #1        |
|                        | Ceph(One shot) | Same as predicate device #1             | PaxScan 4336X: 139μm               | N/A                                |
|                        |                | Same as predicate device #2             | N/A                                | 1717SCC: 127μm                     |
|                        |                | Same as predicate device #1             | PaxScan 2530C: 139μm               | Same as predicate device #1        |
| Magnification          | CT             | SiX 650HD-E : 1.45<br>FXDD-0606CA: 1.44 | SiX 650HD-E: 1.39                  | FXDD-0606CA: 1.44(Patient)         |
|                        | PANO           | C10500D: 1.3                            | C10500D: 1.31                      | N/A                                |
|                        |                | SiX 650HD-E: 1.3                        | SiX 650HD-E: 1.31                  | N/A                                |
|                        |                | XID-C15DP: 1.3                          | XID-C15DP: 1.31                    | N/A                                |
|                        |                | Same as predicate device #2             | N/A                                | FXDD-0606CA: 1.3                   |
|                        | Ceph (Scan)    | Same as predicate device #1             | XID-C24DC: 1.11                    | Same as predicate device #1        |
|                        | Ceph(One shot) | Same as predicate device #1             | PaxScan 4336X: 1.13                | N/A                                |
|                        |                | Same as predicate device #2             | N/A                                | 1717SCC: 1.13                      |
|                        |                | Same as predicate device #1             | PaxScan 2530C: 1.12                | Same as predicate device #1        |
| Scan time              |                | Same as predicate device #1             | CT : below 14sec(Patient)          | Same as predicate device #1        |
|                        |                | Same as predicate device #1             | Pano : below 14sec                 | Same as predicate device #1        |
|                        |                | Same as predicate device #2             | Ceph[Scan type] : below 18sec      | Ceph[Scan type] : below 19ec       |
|                        |                | 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<br>(Cleared under K160525) | RayScan<br>(Cleared under K181452) |
| 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               | <p>1) Computed Tomography(CT) + Panoramic(PANO)=185kg(407.9lb) <math>\pm</math> 10%</p> <p>2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 212.5kg (468.5lb) <math>\pm</math> 10%</p> <p>3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 211kg (465.2lb) <math>\pm</math> 10%</p> <p>4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 211kg (465.2lb) <math>\pm</math> 10%</p> | <p>1) Computed Tomography(CT) + Panoramic(PANO)=150kg(331lb) <math>\pm</math> 10%</p> <p>2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 166kg (366lb) <math>\pm</math> 10%</p> <p>3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 166kg (366lb) <math>\pm</math> 10%</p> <p>4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 166kg (366lb) <math>\pm</math> 10%</p> | <p>1) Computed Tomography(CT) + Panoramic(PANO)=189kg(416.6lb) <math>\pm</math> 10%</p> <p>2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 219kg (482.8lb) <math>\pm</math> 10%</p> <p>3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 217kg (478.4lb) <math>\pm</math> 10%</p> <p>4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 212kg (467.3lb) <math>\pm</math> 10%</p> |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>IEC 60601-1</p> <p>IEC 60601-1-3</p> <p>IEC 60601-2-28</p> <p>IEC 60601-2-63</p> <p>IEC 60601-1-2</p>                                                                                                                                                                                                                                                                                                                                                                           | <p>IEC 60601-1</p> <p>IEC 60601-1-3</p> <p>IEC 60601-2-63</p> <p>IEC 60601-1-2</p>                                                                                                                                                                                                                                                                                                                                                                                                         |

## 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, Scan All viewing software programs have been same with previous 510k submissions; RAYSCAN(K160525).

RCT700 used FPJ filter in CBCT on the RAYSCAN software. And CBCT principle is same previous device RCT700.

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.

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 RCT700 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.

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".

RCT700 is equipped with FXDD-0606CA. FXDD-0606CA is a new SSXI detector, which is used to capture an image in panoramic, CBCT 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 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.

## **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.