August 31, 2023

Ray Co., Ltd.
℅ Sooji Huh
RA Specialist
1F~3F, 4F(Part), 5F, 265, Daeji-Ro, Suji-gu
Yongin-si, Gyeonggi-do 16882
SOUTH KOREA

Re: K232287
Trade/Device Name: RAYSCAN α-Expert3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: August 1, 2023
Received: August 1, 2023

Dear Sooji Huh:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232287

Device Name
RAYSCAN α-Expert3D

Indications for Use *(Describe)*

RAYSCAN α-Expert3D, 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 CBCT technique, to generate dentomaxillofacial 3D images.
The device uses cone shaped x-ray beam projected onto a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.

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

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: Aug 01, 2023

3. Administrative Information

Applicant		Ray Co., Ltd.
Address		1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
Manufacturer	Name	Ray Co., Ltd.
	Address	1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
	Tel	+82-31-605-1000
	Fax	+82-2-6280-5534
Contact Person	Name	Sooji Huh
	Email	Sooji.huh@raymedical.co.kr

4. Device Information

Trade/Proprietary Name		RAYSCAN α-Expert3D
Common Name		Dental Panoramic/Tomography and Cephalometric X-ray System
Classification Name	Device	Computed tomography x-ray system
	Regulation Number	21 CFR 892.1750
	Class	2
	Product Code	OAS
	Review Panel	Radiology

5. Predicate device

Parameter	Predicate Device	Reference Device
Device Name	RAYSCAN α-Expert3D	RCT800
Manufacturer	RAY Co., Ltd	RAY Co., Ltd
510(K) Number	K190812 Special 510k	K230753 Special 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 RAYSCAN α-3D, SM3D, M3DS and M3DL are 3D computed tomography for scanning hard tissues like bone and teeth. By rotating the C-arm, which houses a high-voltage generator, a X-ray tube and a detector on each end, CBCT images of dental maxillofacial structures are obtained by recombining data scanned from the same level at different angles. Functionalities include panoramic image option and cephalometric option.

7. Indication for use

RAYSCAN α-Expert3D, 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 CBCT technique, to generate dento-maxillo-facial 3D images.

The device uses cone shaped x-ray beam projected onto a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.

8. Patient population

The device is intended to acquire diagnostic x-ray images of adult and pediatric individuals/patients without restriction on ethnic group, gender, weight, health status, or condition.

We recommend that patients who undergo X-ray diagnostic radiation exposure be over 5 years old.

9. Comparison with predicate device

The following table provides the summary of the technological characteristics of RAYSCAN α-Expert3D compared to the predicate device

Parameter	Proposed Device	Predicate Device	Reference Device
Manufacturer	RAY Co., Ltd.	RAY Co., Ltd.	RAY CO., Ltd.
Device name	RAYSCAN α-Expert3D	RAYSCAN α-Expert3D	RCT800
510(K) Number	(Special 510K)	K190812 (Special 510K)	K230753 (Special 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	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 CBCT 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.	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 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type	1) CBCT Computed tomography - Patient - Dental Model Scan(Optional) 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type
Functional Option		Same as predicate device #1	Base RAYSCAN α-3D : CT+PANO Option(CEPH) RAYSCAN α-SM3D: CT + PANO + SCAN CEPH RAYSCAN α-M3DS: CT + PANO + One shot(One shot, Standard Type) RAYSCAN α-M3DL: CT + PANO + One shot(One shot, Large Type)	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	N/A	C10900D	FXDD-1724R
		Same as predicate device #1	FXDD-0606CA	FXDD-1012CHA
	PANO	Same as predicate device #1	FXDD-0606CA	FXDD-1724R
		N/A	C10500D	FXDD-1012CHA
	Ceph (Scan)	Same as predicate device #1	XID-C24DC	Same as predicate device #1
	Ceph (One shot)	Same as predicate device #2	PaxScan 4336X	FXRD-1717VA
		N/A	1717SCC	N/A
		Same as predicate device #2	PaxScan 2530C	FXDD-1012CA
Exposure switch Type		Same as predicate device #1	“Deadman” Button type	Same as predicate device #1

Main Components	Same as predicate device #1	Ceph Apparatus	Same as predicate device #1
	Same as predicate device #1	Vertical Carriage	Same as predicate device #1
	Same as predicate device #1	Rotator	Same as predicate device #1
	Same as predicate device #1	X-RAY Generator	Same as predicate device #1
	Same as predicate device #1	X-ray tube	Same as predicate device #1
	Same as predicate device #1	High Frequency Generator	Same as predicate device #1
	Same as predicate device #1	Column	Same as predicate device #1
	Same as predicate device #1	Touch monitor (panel)	Same as predicate device #1
	Detector - CT FXDD-0606CA - PANO FXDD-0606CA - Ceph XID-C24DC(Scan) FXRD-1717VA (One shot, Large Size) FXDD-1012CA (One shot, Standard Size)	Detector - CT C10900D FXDD-0606CA - PANO C10500D FXDD-0606CA - Ceph XID-C24DC(Scan) PaxScan 4336X(One shot, Large Size) 1717SCC(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)	Detector - CT FXDD-1724RA FXDD-1012CHA - PANO FXDD-1724RA FXDD-1012CHA - Ceph XID-C24DC(Scan) FXRD-1717VA(One shot, Large Size) FXDD-1012CA(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 Panoramic exams Cephalometric exams	Same as predicate device #1
Display Type		Same as predicate device #1	TFT LCD type(Normally black) *1280x800 pixel	Same as predicate device #1
Class		Same as predicate device #1	Class I with type B applied parts according to IEC 60601-1	Same as predicate device #1
Focal size		Same as predicate device #1	0.5	Same as predicate device #1
Field of View(CT)		Same as predicate device #1	Max.100x100 mm	FXDD-1724RA : Max.180x160 mm FXDD-1012CHA : Max.200x200 mm
X-ray Voltage(Patient)		Same as predicate device #2	60~90kVp	60~100kVp
X-ray Current(Patient)		Same as predicate device #2	4~17mA	1~17mA
Total Filtration		Same as predicate device #1	Min. 2.8 ㎜ Al equivalent	Same as predicate device #1
Detector Pixel size	CT	N/A	C10900D: 200㎛	FXDD-1724R : 95㎛
		Same as predicate device #1	FXDD-0606CA: 119㎛	FXDD-1012CHA : 124㎛
	PANO	Same as predicate device #1	FXDD-0606CA: 119㎛	FXDD-1724R : 95㎛
		N/A	C10500D: 100㎛	FXDD-1012CHA : 124㎛
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 100㎛	Same as predicate device #1
	Ceph(One shot)	Same as predicate device #2	PaxScan 4336X: 139㎛	FXRD-1717VA : 140㎛
		N/A	1717SCC: 127㎛	N/A
		Same as predicate device #2	PaxScan 2530C: 139㎛	FXDD-1012CA : 124㎛
Magnification	CT	Same as predicate device #2	C10900D:1.39 FXDD-0606CA: 1.44	1.44
	PANO	1.35	C10500D: 1.3 FXDD-0606CA: 1.3	1.31
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 1.11	Same as predicate device #1
	Ceph(One shot)	Same as predicate device #2	PaxScan 4336X: 1.13	FXRD-1717VA : 1.13

		N/A	1717SCC: 1.13	N/A
		Same as predicate device #2	PaxScan 2530C: 1.12	FXDD-1012CA : 1.12
Scan time		Same as predicate device #1	CT : below 14sec(Patient)	CT : below 20sec
		Same as predicate device #1	Pano : below 14sec	Same as predicate device #1
		Ceph[Scan type] : below 19.8sec	Ceph[Scan type] : below 19sec	Ceph[Scan size] : below 20sec
		Ceph[One shot type(S)]: below 0.8sec	Ceph[One shot type]: below 2sec	Same as predicate device #1
		Ceph[One shot type(L)]: below 0.5sec		
Format compatible		Same as predicate device #1	DICOM 3.0 Format compatible	Same as predicate device #1
Image Viewing Software		Same as predicate device #1	RayScan (Cleared under K190812)	RayScan (Cleared under K230753)
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		1) Computed Tomography(CT) + Panoramic(PANO)=150kg(330.7lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 177.5kg (391.3lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 176kg (388lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 176kg (388lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO)=185kg(407.9lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 212.5kg (468.5lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 211kg (465.2lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 211kg (465.2lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO)=189kg(416.6lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph (Scan type)= 219kg (482.8lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Standard size)= 217kg (478.4lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph (One shot type, installed in Large size) 212kg (467.3lb) ± 10%
Type of installation		Same as predicate device #1	Wall or floor mount	Same as predicate device #1
Patient position		Same as predicate device #1	Standing / Wheelchair	Same as predicate device #1

Applicable Standards	Same as predicate device #1	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2	Same as predicate device #1

The product is principally just the same as in the previous 510(k) #K190812.
The complete of differences of the subject device to the predicate #190812 device is as follows
- The maximum X-ray voltage of the tube has been changed from 90kV to 100kV
- The minimum x-ray current of the tube has been changed from 4mA to 1mA
- The Ceph(Scan) scan time has been changed from 20sec to 19.8sec
- Detector (using One-shot).
  However, X-ray voltage, X-ray current, one-shot ceph detector was identified in #K230753

The 510(k) for the existing detector used in our equipment is provided below.

Modality	Detector Model	Cleared	510(k) No.
CT	FXDD-0606CA	No PMA	K182614
Pano	FXDD-0606CA	No PMA	K182614
Scan Ceph	XID-C24DC	No PMA	K181452
One shot Ceph	FXRD-1717VA	No PMA	K213226
One shot Ceph	FXDD-1012CA	No PMA	K213226

10. Safety and Effectiveness Information

RAYSCAN α-Expert3D 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 cleared with previous 510k submissions; RAYSCAN(K190812).
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 maximum X-ray voltage of the tube has been changed from 90kV to 100kV
- The minimum x-ray current of the tube has been changed from 4mA to 1mA
- The Ceph(Scan) scan time has been changed from 20sec to 19.8sec
- Detector (using One-shot).

However, X-ray voltage, X-ray current, one-shot ceph detector was identified in #K230753

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

The software of RAYSCAN α-Expert3D saves patient and image data and offers an inquiry function. In addition, it supports the image generate function intended to obtain images using the RAYSCAN α-Expert3D equipment and various sensors for diagnosis. That has been validated according to the FDA “Guidance for the Content of 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 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 a 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 the FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices”. Bench testing is used to assess whether the parameters required to describe functionalities related to imaging properties of the dental X-ray device and patient dosage satisfy the designated tolerance.

Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4 and IEC 61223-3-7. All test results were satisfactory.

Non-clinical considerations were conducted in accordance with the FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices."
Because the subject device uses the same detector as the predicate device, there are no significant differences between the two devices as a result of non-clinical testing.

Clinical considerations were conducted according to the FDA Guidance "Format for Traditional and Abbreviated 510(k)s". Clinical images were provided, and while these images were not necessary to establish substantial equivalence based on the modifications to the device, they provide further evidence, in addition to the laboratory performance data, to show that the complete system works as intended.

Pediatric information related to the use of this device is provided to users in compliance with FDA guidance "Pediatric Information for X-ray Imaging Device Premarket Notifications".

The features of RAYSCAN α-Expert3D were clinically tested and approved by two licensed practitioners/clinicians. Clinical imaging samples were collected from new detectors on the proposed device at the two offices where the predicate device was installed for the clinical test images. These images were gathered from all detectors installed with RAYSCAN α-Expert3D using protocols with random patient age, gender, and size. A licensed practitioner reviewed the sample clinical images and deemed them to be of acceptable quality for the intended use.

11. 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 RAYSCAN α-Expert3D is safe, effective and substantially equivalent to the predicate device as described herein.