April 18, 2024

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: K232325
Trade/Device Name: RAYSCAN α-Expert
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: August 3, 2023
Received: August 3, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*

K232325

Device Name
RAYSCAN α-Expert

Indications for Use *(Describe)*
The RAYSCAN α- P, SC, OCL, OCS panoramic X-ray imaging system with Cephalostat is an extra-oral source X-ray system, intended for dental radiographic examination of the teeth, jaw, and oral structures, to include panoramic examinations and implantology and for TMJ studies and cephalometry. Images are 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 K232325

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 03, 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-Expert
Common Name		Dental panoramic and cephalometric X-ray system
Classification Name	Device	Extraoral source dental X-ray system
	Regulation Number	21 CFR 872.1800
	Class	2
	Product Code	MUH
	Review Panel	Radiology

5. Predicate device

Parameter	Predicate Device
Device Name	RAYSCAN α-Expert
Manufacturer	RAY Co., Ltd
510(K) Number	K142058 Special 510k
Classification name	Extraoral source dental X-ray system
Regulation number	872.1800
Primary product code	MUH

6. Device Description

RAYSCAN α-Expert (RAYSCAN α-P, SC, OCL, OCS) provides panoramic for scanning teeth, jaw and oral structures. By rotating the C-arm, which houses a high-voltage generator, an all-in-one X-ray tube and a detector on each end, panoramic images of oral and maxillofacial structures are obtained by recombining data scanned from different angles. Functionalities include panoramic image scanning for obtaining images of whole teeth, and a Cephalometric scanning option for obtaining Cephalic images.

7. Indication for use

The RAYSCAN α- P, SC, OCL, OCS panoramic X-ray imaging system with Cephalostat is an extra-oral source X-ray system, intended for dental radiographic examination of the teeth, jaw, and oral structures, to include panoramic examinations and implantology and for TMJ studies and cephalometry. Images are obtained using the standard narrow beam technique.

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-Expert compared to the predicate device

Parameter		Proposed Device	Predicate Device
Manufacturer		RAY Co., Ltd.	RAY Co., Ltd.
Device name		RAYSCAN α-Expert	RAYSCAN α-Expert
510(K) Number		(Traditional 510K)	K142058 (Special 510K)
Common Name		Dental panoramic and cephalometric X-ray system	Dental panoramic and cephalometric X-ray system
Indications for use		The RAYSCAN α- P, SC, OCL, OCS panoramic X-ray imaging system with Cephalostat is an extra-oral source X-ray system, intended for dental radiographic examination of the teeth, jaw, and oral structures, to include panoramic examinations and implantology and for TMJ studies and cephalometry. Images are obtained using the standard narrow beam technique.	The RAYSCAN α- Expert Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.
Mode of Operation		Same as predicate device #1	Continuous operation with intermittent, stated permissible loading
Performance Specification		Same as predicate device #1	1) Panoramic 2) Cephalometric(optional) - One shot type - Scan type
Functional Option		Same as predicate device #1	Base RAYSCAN α-P : PANO Option(CEPH) RAYSCAN α-SC : PANO + SCAN CEPH RAYSCAN α-OCS : PANO + One shot(One shot, Standard Type) RAYSCAN α-OCL : PANO + One shot(One shot, Large Type)
Detector Type	PANO	Same as predicate device #1	C10500D
		Pluto0600X	N/A
	Ceph (Scan)	Same as predicate device #1	XID-C24DC
	Ceph (One shot)	FXRD-1717VA	PaxScan 4336X
		FXDD-1012CA	PaxScan 2530C
Exposure switch Type		Same as predicate device #1	“Deadman” Button type
Main		Same as predicate device #1	Ceph Apparatus

Components		Same as predicate device #1	Vertical Carriage
		Same as predicate device #1	Rotator
		Same as predicate device #1	X-RAY Generator
		Same as predicate device #1	X-ray tube
		Same as predicate device #1	High Frequency Generator
		Same as predicate device #1	Column
		Same as predicate device #1	Touch monitor (panel)
		Detector - PANO C10500D Pluto0600X - Ceph XID-C24DC(Scan) FXRD-1717VA (One shot, Large Size) FXDD-1012CA (One shot, Standard Size)	Detector - PANO C10500D - Ceph XID-C24DC(Scan) PaxScan 4336X(One shot, Large Size) PaxScan 2530C(One shot, Standard Size)
		Same as predicate device #1	Chinrest
		Same as predicate device #1	Head rest
		Same as predicate device #1	Automatic Collimator
		Same as predicate device #1	Exposure switch
		Same as predicate device #1	Emergency stop switch
		Same as predicate device #1	Console PC set
Automatic Collimator		Same as predicate device #1	Panoramic exams Cephalometric exams
Display Type		Same as predicate device #1	TFT LCD type(Normally black) *1280x800 pixel
Class		Same as predicate device #1	Class I with type B applied parts according to IEC 60601-1
Focal size		Same as predicate device #1	0.5
X-ray Voltage(Patient)		60~100kVp	60~90kVp
X-ray Current(Patient)		1~17mA	4~17mA
Total Filtration		2.8㎜Al equivalent	2.6 ㎜ Al equivalent
Detector Pixel size	PANO	Same as predicate device #1	C10500D: 100㎛
		Pluto0600X : 100㎛	N/A
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 100㎛
	Ceph(One shot)	FXRD-1717VA : 140㎛	PaxScan 4336X: 139㎛
		FXDD-1012CA : 124㎛	PaxScan 2530C: 139㎛
Magnification	PANO	1.31	C10500D: 1.3
	Ceph (Scan)	Same as predicate device #1	XID-C24DC: 1.11

	Ceph(One shot)	FXRD-1717VA : 1.13	PaxScan 4336X: 1.13
		FXDD-1012CA : 1.12	PaxScan 2530C: 1.12
Scan time		Same as predicate device #1	Pano : below 14sec
		Ceph[Scan type] : below 19.8sec	Ceph[Scan type] : below 19sec
		Ceph[One shot type(S)]: below 0.8sec	Ceph[One shot type]: below 2sec
		Ceph[One shot type(L)]: below 0.5sec	
Format compatible		Same as predicate device #1	DICOM 3.0 Format compatible
Image Viewing Software		Same as predicate device #1	RayScan (Cleared under K142058)
Image acquisition		Same as predicate device #1	Giga-Ethernet Network
Total Height		Same as predicate device #1	Max 2,296mm
Weight		1) Panoramic(PANO)=150kg(330.7lb) ± 10% 2) Panoramic(PANO) + Cephalostic (Scan type)= 177.5kg (391.3lb) ± 10% 3) Panoramic(PANO) + Cephalostic (One shot type, installed in α-OCS)= 176kg (388lb) ± 10% 4) Panoramic(PANO) + Cephalostic (One shot type, installed in α-OCL)= 176kg (388lb) ± 10%	1) Panoramic(PANO)=148kg(326lb) ± 10% 2) Panoramic(PANO) + Cephalostic (Scan type)= 164kg (362lb) ± 10% 3) Panoramic(PANO) + Cephalostic (One shot type, installed in α-OCS)= 166kg (366lb) ± 10% 4) Panoramic(PANO) + Cephalostic (One shot type, installed in α-OCL)= 166kg (465.2lb) ± 10%
Type of installation		Same as predicate device #1	Wall or floor mount
Patient position		Same as predicate device #1	Standing / Wheelchair
Applicable Standards		IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-63 IEC 60601-1-2

The product is principally just the same as in the previous 510(k) #K142058.
The complete of differences of the subject device to the predicate #142058 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
- Added new Pano Detector(Pluto0600X)
- Change of the 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.
Pano	C10500D	No PMA	K142058
Pano	Pluto0600X	No PMA	K222666

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-Expert 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), Scan All viewing software programs have been cleared with previous 510k submissions; RAYSCAN(K142058).
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
- Added new Pano Detector(Pluto0600X)
- 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-Expert 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-Expert 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. 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".

The main measure of clinical performance for RAYSCAN α-Expert is determined to be image quality. The clinical performance of RAYSCAN α-Expert were clinically tested and approved by two licensed

practitioners/clinicians. These images were gathered from all detectors of RAYSCAN α-Expert 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. These results are substantially equivalent to the evaluation performed on predicate device.

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-Expert 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-Expert 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-Expert is safe, effective and substantially equivalent to the predicate device as described herein.