



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

RAY Co. Ltd.
% Mr. Changhwan Lee
Regulatory Affairs Manager
332-7 Samsung 1-ro, Hwaseong-si
445-330 Gyeonggi-do
REPUBLIC OF KOREA

April 15, 2016

Re: K160788
Trade/Device Name: RIOScan (RPS500)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 15, 2016
Received: March 22, 2016

Dear Mr. 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

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

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the printed name and title.

FOR

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

Enclosure

Indications for Use

510(k) Number (if known)
K160788

Device Name
Trade Name: RIOScan
Proprietary Name: RPS500
Common Name: Computed radiography scanner system

Indications for Use (Describe)

This system is a digital intraoral dental radiographic imaging system intended for use by dentists and dental sub-specialists. The system captures, digitizes, displays and stores diagnostic intraoral radiographic images.

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
PRASStaff@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."

510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date: February 15, 2016

APPLICANT RAY Co., Ltd

ADDRESS #332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 443-823, Korea

Manufacturer RAY Co., Ltd
332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 443-823, Korea

TEL : +82-31-605-1000

FAX : +82-2-6280-5534

Contact Person Changwhan.Lee
e-mail : ch0406.lee@raymedical.co.kr

Device Name

Trade Name: RIOScan

Proprietary Name: RPS500

Common Name: Computed radiography scanner system.

Classification

Regulation Name: Extraoral Source X-ray System.

Classification name: X-ray, Extraoral, Source, Digital

Regulatory Number: 21 CFR 872.1800

Class: II

Product code: MUH

Panel: Radiology

Description

RIOScan(Model RPS500) is Computed radiography system for dental intraoral applications. Imaging plates (i.e, storage phosphor plates) are exposed in the same way as traditional x-ray film. The x-ray images on these plates are then fed into a small computed radiography system and scanned using a laser. The scanned image data from the plates is digitized and the images are displayed on a monitor and saved to computer.

RPS500 is capable of scanning the X-ray exposed imaging plates at various speed, sizes and resolutions. Once an imaging is scanned, the image data is automatically erased from the plate and the plate ejected reuse.

RIOScan digital scanner doesn't have a wireless option for data transmission

Indication for use

This system is a digital intraoral dental radiographic imaging system intended for use by dentists and dental sub-specialists. The system captures, digitizes, displays and stores diagnostic intraoral radiographic images.

Predicate device

- 1) Predicate device-1
 Manufacturer: PaloDEx Group Oy
 Device: DIGORA Optime (DXR-60)
 510(k) Number: K133231
- 2) Predicate device-2
 Manufacturer: 3D Imaging & Simulations Corp
 Device: FireCR Dental Imaging SYstem
 510(k) Number: K131442

Statement of Substantial Equivalence

Parameter	Proposed Device	Predicated Device	Predicated Device
Manufacturer	RAY Co., Ltd	PaloDEx Group Oy	3D Imaging & Simulations Corp
Device Name	RIOScan	DIGORA® Optime (DXR-60)	FireCR DENTAL IMAGING SYSTEM
510(K) Number	-	K133231	K131442
Feature			

Intended use	The RIOScan(Model RPS500)is a digital intraoral dental radiographic imaging system intended for use by dentists and dental sub-specialists. The system captures, digitizes, displays and stores diagnostic intraoral radiographic images.	SOREDEX® DIGORA® Optime system is intended to be used only by dentist and other qualified dental professional to process x-ray images exposed to the imaging plates from the intraoral complex of the skull	The FireOR Dental imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media
Indications for use	The RIOScan scanner system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.	The DIGORAO® Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.	The FireCR Dental imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media
Device Description	<p>RIOScan(Model RPS500) is Computed radiography system for dental intraoral applications. Imaging plates (i.e, storage phosphor plates) are exposed in the same way as traditional x-ray film. The x-ray images on these plates are then fed into a small computed radiography system and scanned using a laser. The scanned image data from the plates is digitized and the images are displayed on a monitor and saved to computer. RPS500 is capable of scanning the X-ray exposed imaging plates at various speed, sizes and resolutions. Once an imaging is scanned, the image data is automatically erased from the plate and the plate ejected reuse. RIOScan digital scanner doesn't have a wireless option for data transmission</p>	<p>DIGORA® Optime(DXR-60) is a digital radiography system for intra oral imaging plates located in disposable bags. The system may be used with all x-ray equipment which is designed for intra oral radiography. The image is recorded on reusable imaging plate which substitutes for conventional x-ray film or digital sensor. The x-ray energy absorbed in the imaging plate remains stored as a latent image. When fed to the device the stored energy is released as an optical emission proportional to the stored energy when the imaging plate is stimulated pixel by pixel by a scanning laser. An optical system collects the emission for photo electronic system, which converts the emission to digital electronic signals. These signals are processed in a computer system which formats and stores the signals. Further image processing, display and achieving are carried out with auxiliary software.</p>	<p>The FireCR Dental is Computed Radiography Reader which produces the X-ray diagnostic image in digital format instead of using traditional screens and film. This device utilizes reusable X-ray storage phosphor plate (imaging Plate) that is sensitive to X-ray and stores latent image when it is exposed to X-ray. After X-ray exposure to the X-ray storage phosphor plate, X-ray storage phosphor plate is scanned by means of laser in the device. Latent image in the X-ray storage phosphor plate is released in a form of light by laser scanning. Then the light is collected and converted into a form of digital image. The signal processing is made to the digital image data such as the digital filtering, the gain & offset correction and flat fielding. The image can then be viewed on a computer workstation, adjusted if necessary, then stored locally, sent to an archive, printed or sent to PACS system. After acquisition of latent image from the X-ray storage phosphor plate, it is erased thoroughly to be reused.</p>
Available Image plate	Size: 0, 1, 2, 3, 4	Size: 0, 1, 2, 3	Size: 0, 1, 2, 3
Image plate size	<p>Size 0 22 x 35 mm Size 1 24 x 40 mm Size 2 31 x 41 mm Size 3 27 x 54 mm Size 4 57 x 76 mm</p>	<p>Size 0 22 x 31 mm Size 1 24 x 40 mm Size 2 31 x 41 mm Size 3 27 x 54 mm</p>	<p>Size 0 22 x 31 mm Size 1 24 x 40 mm Size 2 31 x 41 mm Size 3 27 x 54 mm</p>

Resolution (Theoretical)	HS 9 lp/mm HR 16 lp/mm SHR 21 lp/mm	16.7 lp/mm	HS 7.8 lp/mm HR 14.3 lp/mm
Pixel size (selectable)	24 μm (High speed) 32 μm (Super resolution) 56 μm (Super High resolution)	30 μm (Super resolution) 60 μm (High resolution)	35 μm (Super resolution) 64 μm (High resolution)
Image data bit depth	14 bit	14 bit	16bit
Operating voltage	24 VDC (External PSU 100-250 Vac, 50/60Hz)	24 VDC (External PSU 100-250 Vac, 50/60Hz)	24 VDC (External PSU 100-250 Vac, 50/60Hz)
Laser safety classification	Class 1 laser product EN60825-1:2014(Third Edition)	Class 1 laser product EN60825-1:2007	Class 1 laser product EN60825-1:2007
Interface	Ethernet RJ-45 10/100 Mbs LAN	Ethernet RJ-45 10/100 Mbs LAN	Ethernet RJ-45 10/100 Mbs LAN
MTF	More than 35% at 3 lp/mm	32% at 3 lp/mm	34% at 3 lp/mm
DQE	More than 10% at 3 lp/mm	10% at 2.4 lp/mm	10% at 2.6 lp/mm
Erasing	Auto	Auto	Auto
Dimensions (W x H x D)	170 mm x 260 mm x 278 mm	152 mm x 227 mm x 308 mm	265 mm x 120 mm x 318 mm
Weight	3.5 kg	3.5 kg	4.7 kg

The intended use, constructions, construction materials, technical characteristics and safety characteristics between RPS500 and Its predicate device are same. Accordingly we can claim the substantially equivalence of RPS500 to the predicate device.

Safety and Effectiveness Information:

Electrical, mechanical and environmental safety testing according to standard of IEC 60601-1(2005+ CORR.1(2006)+CORR.2(2007) was performed. EMC testing was conducted in accordance with the standard IEC 60601-1-2(2007).

The software of RPS500 has been validated according to FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and applicable requirements contained in the guidance document.

The software of RPS500 is based on a RIOSenser software(K143000).

Software release version

Ver 1.0.0.0	Ver 1.1.1.0
Initial release for RIOSensor (RIS500) K143000	Initial release for RIOScan (RPS500) K160788

Compares the characteristics

	Ver 1.0.0.0	Ver 1.1.1.0	Remark
Resolution	1280 X 800 or higher	1280 X 800 or higher	
Graphic	Video RAM over 512MB	Video RAM over 512MB	
Language	C#	C#	
Development Library & Platform	Net Framework 4.0 Microsoft DirectX SDK	Net Framework 4.0 Microsoft DirectX SDK	
Configuration Intraoral sensor type	RIO Sensor (RIS 500 -K143000)	RIOSensor (RIS 500 -K143000) RIOScan	Add the device (RIOScan)
Image Processing	RIOSensor Image Func.	RIOSensor Image Func. RIOScan Image Func.	Add the device (RIOScan)
Export	CD/DVD export USB export	CD/DVD export USB export	
Print	Paper print and DICOM print	Paper print and DICOM print	
OS	Window 7,8(32or 64bit)	Window 7,8(32or 64bit)	

Similarities:

In case of the RioView Ver1.0.0.0 for RioSensor(RIS500) and RioView Ver 1.1.1.0 for RioScan(RPS500), similarities exist in the resolution, graphic, OS, method of export and print. Both software version operating principles and operating methods are also similar, power is supplied through the USB interface port for operation and Data is transmitted to a personal PC.

Differences:

There are no difference between RioView Ver 1.0.0.0 for RioSenser(RIS500) and RioView Ver 1.1.1.0 for RioScan(RPS500) as far as purpose of use, operating principles and operating methods are concerned.

The main differences exist in available device, have been added the RioScan(RPS500) to available device in RioView Ver 1.1.1.0.

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*".

"In the case of the RioScan system, clinical images are not necessary to establish substantial equivalence, and the non-clinical performance data alone show that the device works as intended. All test results were satisfactory."

The tests include the MTF(Modulation Transfer Function) and DQE(Detective Quantum Efficiency) of detector. MTF of detector shows the resolution more than 92% at 1 lp/mm and The DQE of detector shows the resolution more than 45% at 1 lp/mm.

Base on the Non-Clinical Test report, Even though the pixel size and active area of predicate detectors are different, the diagnostic image quality of RPS500 detector is equal or better than that of predicate device and there is no significant difference in efficiency and safety.

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 RPS500 is safe and effective to perform its intended use as well as substantially equivalent to the predicate device.