DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ray Co., Ltd.
% Mr. Andrew H. Paeng
Consultant
4747 Hoen Avenue
SANTA ROSA CA 95405

January 23, 2015

Re: K143000
Trade/Device Name: RIO Sensor (RIS 500)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 28, 2014
Received: October 30, 2014

Dear Mr. Paeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143000

Device Name
Trade Name: RIOSensor
Proprietary Name: RIS500
Common Name: Intraoral Imaging Unit

Indications for Use *(Describe)*
This system is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.

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.

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5. 510(K) Summary

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:

APPLICANT RAY Co.,Ltd

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Device Name

Trade Name: RIOSensor
Proprietary Name: RIS500
Common Name: Intraoral Imaging Unit

Classification

Classification name: solid state x-ray imager (flat panel/digital imager)
Regulatory Number: 21 CFR 892.1680
Class: II
Product code: MQB
Panel: Radiology

Description

RIOSensor(Model RIS500) is intended to acquire real-time, clinical digital intraoral X-ray images using a solid-state imaging sensor. This system consists of the CMOS sensor and software for image display. This system senses the onset of the X-ray exposure and automatically acquires and save the image data to a PC (software).

Indication for use

This system is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.

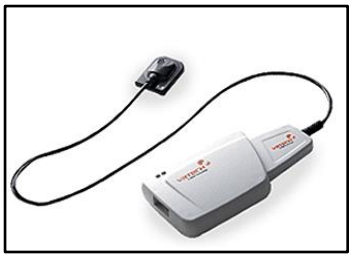
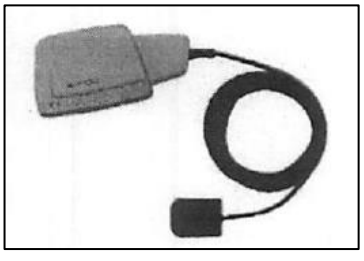
"CAUTION: Federal (US) law restricts the sale of this device to, or on the order of, licensed professionals.

Predicate device

1) Predicate device-1
   Manufacturer: HUMANRAY Co., Ltd.
   Device: EzSensor T
   510(k) Number: K121132

2) Predicate device-2
   Manufacturer: E-WOO TECHNOLOGY
   Device: EzSensor
   510(k) Number: K090526

Statement of Substantial Equivalence

Parameter	Proposed Device	Predicated Device	Predicated Device
Manufacturer	RAY Co., Ltd	HUMANRAY Co., Ltd	E-WOO Technology Co., Ltd.
Device Name	RIS500	EzSensor P	EzSensor
510(K) Number	K143000 Traditional 510k	K121132 Special 510k	K090526 Traditional 510k
Feature			

Indications for use	This system is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.	EzSensor P, Intra-oral Imaging System, isintended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.	Indicated for intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentist.
Device Description	RIOSensor(Model RIS500) is intended to acquire real-time, clinical digital intraoral X-ray images using a solid-state imaging sensor. This system consists of the CMOS sensor and software for image display. This system senses the onset of the X-ray exposure and automatically acquires and save the image data to a PC (software).	EzSensor P is a solid state x-ray imager designed for dental radiographic applications, The EzSensot P digital intraoral sensor provides digital image capture to replace radiographic film/screen system in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port.	The EzSensor is a solid state x-ray imager designed for dental radiographic applications, The EzSensor provides digital image capture for conventional film/screen radiographic dental examinations. The device is used to replace radiographic film/screen system in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port
Sensor Dimension	Size 1: 39x25 mm Size 2: 42x30 mm	Size “1.5”: 38.7x29.2 mm Size “2.0”: 42.8x31.5 mm	Size “1.0”: 35.7x25.2 mm Size “1.5”: 38.7x29.2 mm
Sensor Thickness	5.6 mm	4.95 mm	4.95mm
Active Area(mm)	Size 1: 39x25 Size 2: 42x30	Size “1.5”: 24.01x33.04 Size “2.0”: 26.04x36.05	Size “1.0”: 20.02x30.03 Size “1.5”: 24.08x31.85
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module	Integrated USB 2.0 module
Pixel size	20x20 ㎛	20x20 ㎛	35x35 ㎛
Pixel Matrix	Size 1: 1000x1500 pixel Size 2: 1300x1700 pixel	Size “1.5”: 1200x1650 pixel Size “2.0”: 1300x1800 pixel	Size “1.0”: 572x858 pixel Size “1.5”: 686x944 pixel
Pixel Pitch	20x20 ㎛	20x20 ㎛	35x35 ㎛
Theoretical Resolution	25 lp/mm	25 lp/mm	14.3 lp/mm
MTF	More than 30% at 6 lp/mm	More than 30% at 6 lp/mm	More than 30% at 6 lp/mm
DQE	More than 40% at 2.5 lp/mm	More than 40% at 2.5 lp/mm	More than 40% at 2.5 lp/mm

The intended use, constructions, construction materials, technical characteristics and safety characteristics between RIS500 and Its predicate device are same.

Accordingly we can claim the substantially equivalence of RIS500 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 RIS500 has been validated according to FDA "*Guidance for the Content d Premarket Submissions for Software Contained in Medical Devices"* and applicable requirements contained in the guidance document.

Bench testing was conducted according to FDA Guidance *"Format for Traditional and Abbreviated 510(k)s, section 18, Performance Testing – Bench"*
Bench testing is used to assess whether or not the parameter measured required for describing functionalities related to imaging properties of the dental X-ray device and patient dosage satisfies the designated tolerance.
Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4.
All test results were satisfactory.

Non-clinical considerations were conducted in accordance with FDA Guidance *"Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices"*.
All test results were satisfactory.
The tests include the MTF(Modulation Transfer Function) and DQE(Detective Quantum Efficiency) of detector. MTF of detector shows the resolution more than 30% at 6 lp/mm and The DQE of detector shows the resolution more than 40% at 2.5 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 RIS500 detector is equal or better than that of predicate device and there is no significant difference in efficiency and safety.

Clinical considerations were conducted according to FDA Guidance *"Format for Traditional and Abbreviated 510(k)s, section 20"*.
For clinical testing, two licensed practitioners/clinicians observed and verified that Intraoral Imaging Unit from RIOSensor(Model name: RIS500).

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 RIS500 is safe and effective to perform its intended use as well as substantially equivalent to the predicate device.