



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

Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K150797

Trade/Device Name: Digital Dental Intra Oral Sensor, EzSensor Smart:
IOS-U15VF, IOS-U10VF, IOS-U15IF, IOS-U10IF, IOS-U15VB, IOS-U10VB, IOS-
U15IB, IOS-U10IB, HDI-U15DB, HDI-U10DB, HDI-U15DF, HDI-U10DF
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 24, 2015
Received: April 29, 2015

Dear Mr. Kim:

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 black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, semi-transparent "FDA" watermark is visible behind the signature.

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

Indications for Use

510(k) Number (if known)

K150797

Device Name

EzSensor Smart

Digital Dental Intra Oral Sensor IOS-UI5VF, IOS-UI OVF, IOS-UI5IF, IOS-UI OI, IOS-UI5VB, IOS-UIOVB, IOS-UI5IB, IOS-UI OIB, HDI-UI5DB, HDI-UIODB, HDI-UI5DF, HDI-UI ODF

Indications for Use (Describe)

Digital Dental Intra Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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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.”

1. 510(k) Summary

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

Date 510K summary prepared: March 25, 2015

Submitter's Name, address, telephone number, a contact person:

Submitter's Name : Rayence Co., Ltd.
Submitter's Address: 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Submitter's Telephone: +82-31-8015-6459
Contact person: Mr. Kee Dock Kim / RA Team Manager / +82-31-8015-6459
Official Correspondent: Dave Kim (davekim@mtech-inc.net)
(U.S. Designated agent)
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
Fax: +713-583-8988

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name: IOS-U15VF, IOS-U10VF, IOS-U15IF, IOS-U10IF, IOS-U15VB,
IOS-U10VB, IOS-U15IB, IOS-U10IB, HDI-U15DB, HDI-U10DB,
HDI-U15DF, HDI-U10DF
Common Name: EzSensor Smart, Digital Dental Intra Oral Sensor
Regulatoin number: 21 CFR 872.1800
Classification Name : Extraoral source X-ray system
Product Code: MUH

Predicate Device :

Manufacturer : Rayence Co., Ltd.
Device : EzSensor
510(k) Number : K090526
The Regulation Number : 21 CFR 872.1800

Classification Name : Extraorla Source X-ray System
Primary Product Code : MUH

2. Device Description

Digital Dental Intra Oral Sensor is a device which acquires digital intra-oral images. Direct digital systems acquire images with a sensor that is connected to a computer to produce an image almost instantaneously following exposure. The primary advantage of direct sensor systems is the speed with which images are acquired. For patient comfort, the ergonomic design is based on human intraoral anatomy.

- Excellent image quality based on advanced CMOS technology
- A more comfortable sensor ergonomic shape for the human oral structure
- Lower dose exposure (Compared to film sensor)
- Enhanced durability
- Easy-to-use USB interface

3. Indication for use

Digital Dental Intra Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

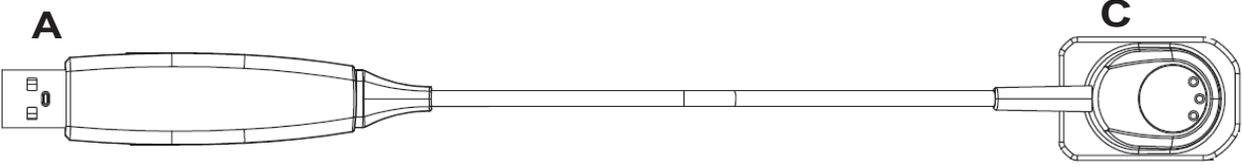
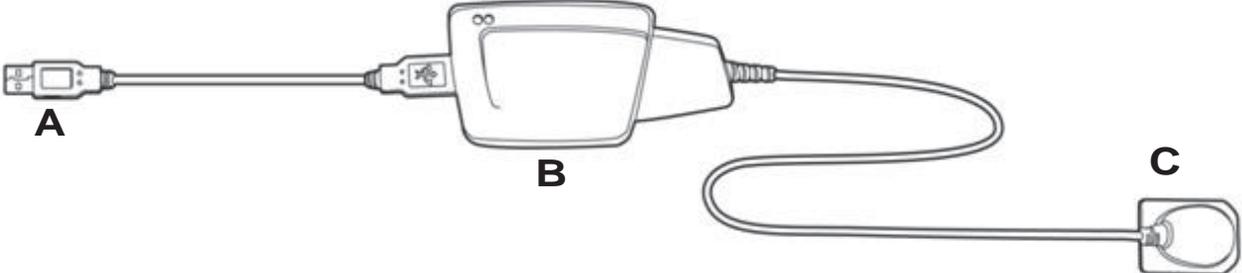
4. Summary of Design Control Risk management

The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

5. Summary of the technological characteristics of the device compared to the predicate device

Digital Dental Intra Oral Sensor described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, EzSensor of Rayence Co., Ltd.

5. 1 Feature

Proposed : IOS-U15VF AND 11MODELS		
		
Predicate : EzSensor		
		
<p>A : USB Connector B : Interface Board C : Sensor Head</p>		

Mechanical design change point

	Proposed	Predicate
A	1) Ensure robustness by using the stainless steel material to the inside of the frame. 2) Soft silicone material surrounds the USB Connector to reduce the protected from a potential external impact when it is positioned behind the PC.	No stainless steel frame No silicon material protecting USB connector
B	1) Easy-to-use USB Interface with the interface board already integrated with the A.	The interface board requires a separate USB cable to connect to PC
C	1) structure is similar 2) Improved waterproofing structure (prevents moisture permeation of external environment).	-

The potential risks of IOS-U15VF AND 11 MODELS such as electroic shock, device failure, misdiagnosis, tissue damage, serious leakage current, etc... were analyzed by conducting complete verification for IEC/EN 60601-1 and drop & vibration test. (Completed the risk analysis for A,C above).

While applying the stainless steel material to the inside of the frame, soft silicon material surrounds the exterior of the USB connector to reduce the protected from a potential external impact. Additional risk analysis was conducted to mitigate the potential risks that may arise with respect to leakage current, sensor fracture or breakage, and cable disconnection. The risk mitigation measures were satisfactory to manage the new risks identified and the residual risks were within acceptable limits.

5. 2 Characteristic

Characteristic	Proposed Rayence Co., Ltd. IOS-U15VF, IOS-U10VF, IOS-U15IF, IOS-U10IF, IOS-U15VB, IOS-U10VB, IOS-U15IB, IOS-U10IB, HDI-U15DB, HDI-U10DB, HDI-U15DF, HDI-U10DF	Predicate Rayence Co., Ltd. <i>EzSensor</i>
Feature		
510(k) number	-	K090526
Indications for use	Intra-Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.	EzSensor, an Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.
Sensor Dimension(mm)	Size 1.0: 37.6 x 25.4 Size 1.5: 39.5 x 29.2	Size 1.0: 35.7 x 25.2 Size 1.5: 38.7 x 29.2
Sensor Thickness(mm)	4.8	4.9
Active Pixel Area(mm)	Size 1.0: 1352 x 2028 pixels (20.00 x 30.01 mm) 676 x 1014 pixels @Binning Mode Size 1.5: 1620 x 2230 pixels (23.98 x 33.00 mm) 810 x 1115 pixels @Binning Mode	Size 1.0: 20.02 x 30.03 Size 1.5: 24.08 x 31.85

USB Module	Integrated USB 2.0 module		Integrated USB 2.0 module
Pixel Pitch(μm)	Full Resolution	14.8	35
	Binning mode	29.6	
DQE(6 lp/mm)	Full Resolution	0.38	0.123
	Binning mode	0.34	
MTF(6 lp/mm)	Full Resolution	0.642	0.382
	Binning mode	0.630	
Typical dose range(μGy)	Incisor & Canine : 300 ~ 500 μGy / Molar: 400 ~ 600 μGy		
Viewer Software	Easydent Dental Imaging Viewer EzDent i (K131594)		Easydent

5. 3 Viewer Software

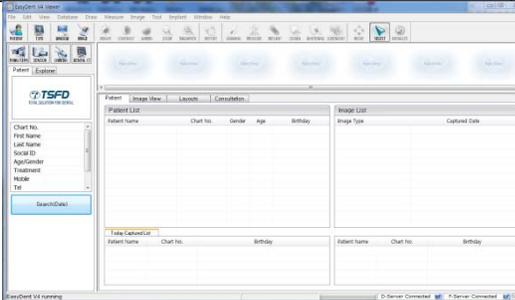
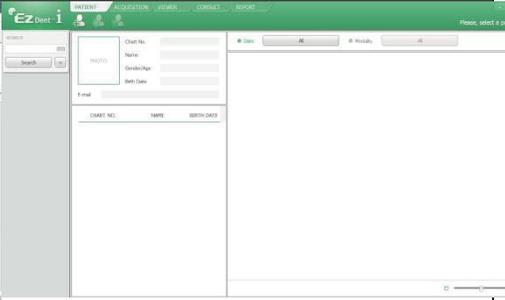
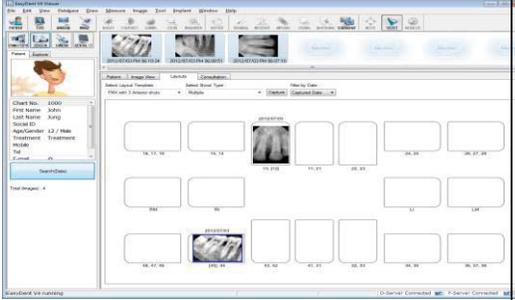
Characteristic	Proposed Rayence Co., Ltd. IOS-U15VF, IOS-U10VF, IOS-U15IF, IOS-U10IF, IOS-U15VB, IOS-U10VB, IOS-U15IB, IOS-U10IB, HDI-U15DB, HDI-U10DB, HDI-U15DF, HDI-U10DF	Predicate Rayence Co., Ltd. EzSensor
Viewer Software	Easydent (Same viewer software used for EzSensor Soft, K143753) Dental Imaging Viewer EzDent i (K131594)	Easydent

With the identical hardware configuration, the subject device has different model names distinguished by the sensor size and type of image viewing software utilized. The software functions include the patient information management, image capture, and an image viewer.

Easydent/Dental Imaging Viewer and EzDent i image viewing software have the same functionality and performance. The main difference is the design of the user interface (UI) and new consulting simulation tool for EzDent i. EzDent i requires a license registration for a fee whereas Easydent/Dental Imaging Viewer is provided free of charge.

Viewer Software	510(k) Number	Manufacturer	Comment
Easydent	Same viewer software used for EzSensor Soft, K143753	Rayence Co., Ltd.	Easydent and Dental Imaging Viewer is same Software. Difference is that CI is displayed on the UI for marketing purposes.
Dental Imaging Viewer	-	Rayence Co., Ltd.	
EzDent i	K131594	EWOO SOFT	-

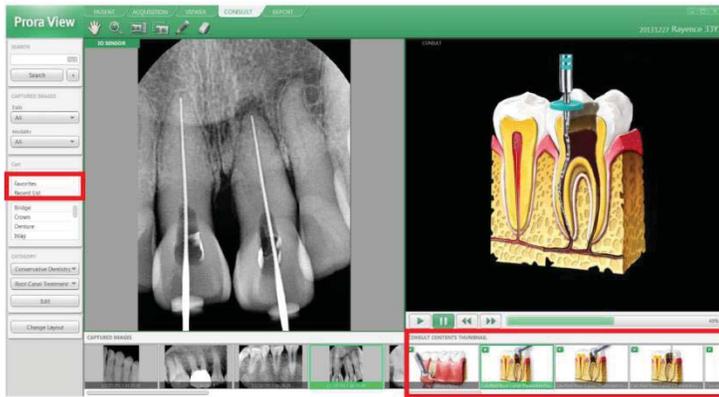
1) Difference for Easydent/Dental Imaging Viewer and EzDent i

	Easydent Dental Imaging Viewer	EzDent i
Function	Patient View Acquisition Consultation Report	Patient View Acquisition Consultation Report License
The initial screen shot		
Image Acquisition screen		

2) Features added to EzDent i

2.2.1. Acquisition_ CONSULT Tab

Acquisition_ CONSULT Tab is a consulting tool and provides a video simulation of the treatment process with the acquired images in sequence.



2.2.2. License

EzDent i requires a fee based license registration whereas EasyDent is provided free of charge.

6. Summary of Performance Testing

The IOS-U15VF AND 11MODELS are the modification of EzSensor, FDA cleared predicate device under the document number K090526 and the performance of both subject and predicate devices are substantially equivalent in terms of safety and effectiveness.

The intended use, application and detector type for both IOS-U15VF AND 11MODELS and the predicate device are identical. Both IOS-U15VF AND 11MODELS and EzSensor use the same amorphous silicon alloy and materials for fluorescent as the sensing means. The performance test results indicate that the IOS-U15VF AND 11MODELS detector performed consistently better than EzSensor, the predicated device, in terms of image quality. No additional safety risk is identified in the bench test: Non-clinical report.

With a smaller measured pixel size of IOS-U15VF AND 11MODELS, both in full resolution and in 2x2 binning mode, DQE, MTF, and linear response to X-ray exposure test demonstrated that IOS-U15VF AND 11MODELS has consistently performed better than EzSensor, the predicate sensor. Especially, the response of IOS-U15VF AND 11MODELS as a function of X-ray exposure is very linear and has better linearity, close to 1, than EzSensor in the same dynamic range.

Total 30 sets of radiographic image samples were reviewed by a licensed dentist. Based on the reviewer's conclusion, IOS-U15VF AND 11MODELS (Binning Mode and Full Resolution Mode) produce images which are superior EzSensor in terms of diagnostic quality in most cases. There is negligible difference between Binning Mode and Full Resolution Mode. All images from both devices present no significant difficulty in evaluating a range of anatomic structures necessary to provide a correct diagnosis while minimizing radiation exposure to patients.

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 subject devices operate as indicated.

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1: 2005 + CORR.1(2006) + CORR(2007) (Medical electrical equipment Part 1:General requirements for basic safety and essential performance) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007.

7. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Rayence Co., Ltd. concludes that IOS-U15VF AND 11MODELS is safe and effective and substantially equivalent to predicate device as described herein.