



Food and Drug Administration
10903 New Hampshire Avenue
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Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

November 10, 2015

Re: K153060

Trade/Device Name: EzSensor Classic, EzSensor HD, HDI-P, HDI-S, Digital
Dental Intra Oral Sensor
IOS-U20VF, IOS-U15VF, IOS-U10VF, IOS-U20IF, IOS-U15IF,
IOS-U10IF, IOS-U20VB, IOS-U15VB, IOS-U10VB, IOS-U20IB
IOS-U15IB, IOS-U10IB, HDI-U20DB, HDI-U15DB, HDI-U10DB
HDI-U20DF, HDI-U15DF, HDI-U10DF

Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 16, 2015
Received: October 21, 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 Ochs". The signature is written in a cursive style with a light grey shadow effect behind the text.

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)

K153060

Device Name

EzSensor Classic, EzSensor HD, HDI-P, HDI-S, Digital Dental Intra Oral Sensor
IOS-U20VF, IOS-U15VF, IOS-U10VF, IOS-U20IF, IOS-U15IF, IOS-U10IF, IOS-U20VB, IOS-U15VB
IOS-U10VB, IOS-U20IB, IOS-U15IB, IOS-U10IB, HDI-U20DB, HDI-U15DB, HDI-U10DB, HDI-U20DF
HDI-U15DF, HDI-U10DF

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: October 16, 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)
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: EzSensor Classic, EzSensor HD, HDI-P, HDI-S
Digital Dental Intra Oral Sensor
(IOS-U20VF, IOS-U15VF, IOS-U10VF,
IOS-U20IF, IOS-U15IF, IOS-U10IF,
IOS-U20VB, IOS-U15VB, IOS-U10VB,
IOS-U20IB, IOS-U15IB, IOS-U10IB,
HDI-U20DB, HDI-U15DB, HDI-U10DB,
HDI-U20DF, HDI-U15DF, HDI-U10DF)

Common Name: 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 : 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
510(k) Number : K150797 (Decision Date – May 1, 2015)
The Regulation Number : 21 CFR 872.1800
Classification Name : Extraoral 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
- 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.

A new sensor size 2.0 is added to the existing sensor sizes 1.0 and 1.5 of the predicate device.

These differences do not raise the questions of safety or effectiveness. Based on the laboratory testing results submitted in this 510k, we conclude that the subject device is substantially equivalent to the predicate device.

The potential risks for new sensor size 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.

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.

Characteristic	Proposed	Predicate
<i>Device's model name</i>	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 IOS-U20VF, IOS-U20IF, IOS-U20VB, IOS-U20IB, HDI-U20DB, HDI-U20DF	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
<i>Feature</i>		

510(k) number		-	K150797
Indications 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.	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.
Sensor Dimension(mm) ($\pm 10\%$)		Size 1.0: 36.8 x 25.4 Size 1.5: 39.5 x 29.2 Size 2.0: 42.9 x 31.3	Size 1.0: 37.6 x 25.4 Size 1.5: 39.5 x 29.2
Sensor Thickness(mm)		4.8	4.8
Active Area(mm)		Size 1.0: 30.01 x 20.01 Size 1.5: 33.00 x 23.98 Size 2.0: 35.99 x 25.99	Size 1.0: 30.01 x 20.00 Size 1.5: 33.00 x 23.98
USB Module		Integrated USB 2.0 module	Integrated USB 2.0 module
Pixel Pitch(μm)	Full Resolution	14.8	14.8
	Binning mode	29.6	29.6
DQE (6 lp/mm)	Full Resolution	0.38	0.38
	Binning mode	0.34	0.34
MTF (3 lp/mm)	Full Resolution	0.642	0.642
	Binning mode	0.630	0.630
Typical dose range(μGy)		Incisor & Canine : 300 ~ 500 / Molar: 400 ~ 600	
Viewer Software		Easydent or EzDent-i(K150747)	Easydent or EzDent-i(K150747)

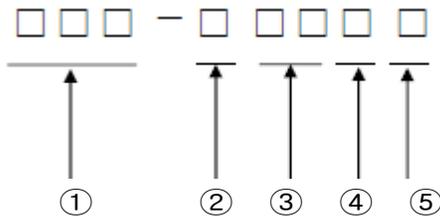
With the identical hardware configuration, the subject device has different model names distinguished by the sensor size and type of image viewing software utilized. The software functions include the patient information management, image capture, and an image viewer.

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

Dental Imaging Viewer	-	Rayence Co., Ltd.	the UI for marketing purposes.
EzDent i	K150747	EWOO SOFT	-

**NOTE : Naming rules*



- ① digit means buyer information- IOS, HDI
- ② digit means type
- ③ digit means size- 10: 1.0 15: 1.5 20: 2.0
- ④ digit means operated using software
V: Easydent I: EzDent-i D: Dental Imaging Viewer(=Easydent)
- ⑤ digit means function Mode- F: Full mode B: Binning mode

- Representative model description

Model	Information
IOS-U20VF	1. buyer : IOS 2. Sensor Type : CMOS Image Sensor 3. Sensor Size : 2.0 4. Version of SW : Easydent 5. Mode : Full

6.Summary of Performance Testing

The intended use, application and detector type of IOS-U20VF AND 17MODELS is the same as that of the predicate device, IOS-U20VF AND 11MODELS.

Both the subject and predicate devices use the same amorphous silicon alloy and materials for fluorescent as the sensing means. The performance test result indicates that the IOS-U20VF AND 17MODELS detector performed equally the predicated device; IOS-U20VF AND 11MODELS and no additional safety risk is identified in the bench test: Non-clinical report.

Non-clinical according to FDA Guidance “Guidance for the Submissions of 510(k)’s for Solid State X- ray Imaging Devices” was performed.

Clinical images were not necessary to establish substantial equivalence based on the modifications to the device. The laboratory performance data shows that the subject device operates similar to the predicate device.

The DQE, MTF and linear response to X-ray exposure test demonstrated that the subject sensor performed equivalently compared to the predicate device with the same dynamic range.

Electrical, mechanical, environmental safety and performance testing were performed 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). EMC testing was conducted in accordance with standard IEC 60601-1-2:2007.

7. 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. Rayence Co., Ltd. concludes IOS-U20VF AND 17MODELS is safe and effective and substantially equivalent to predicate device as described herein.