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: January 3, 2014

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

Submitter's Name :	Rayence Co., Ltd.
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(U.S. Designated agent)	
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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:	HDI 2000, HDI 2000A
Common Name:	Medical Image Processing Unit
Classification Name :	21CFR892.1680 / Stationary x-ray system
Product Code:	MQB

Predicate Device :

Manufacturer	: Rayence Co., Ltd.
Device	: EzSensor P
510(k) Number	: K121132 (Decision Date – MAY. 10. 2012)

Device Description :

The HDI 2000 / HDI 2000A Intra-oral imaging system is a device which acquires digital image. Direct digital systems acquire images with a solid-state 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. The sensor is connected by a wire to an analog-to-digital USB box, which is connected to the computer. Images are produced within seconds of sensor exposure. The wire length from a direct sensor is about 3 meters and less. The USB box connects to the USB 2.0 port of the computer.

Indication for use :

HDI 2000 / HDI 2000A, 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.

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

The The indications for use, material, form factor, performance, and safety characteristics of HDI 2000 / HDI 2000A described in this 510(k) are the same as that of the predicate device, EzSensor P of Rayence Co., Ltd.

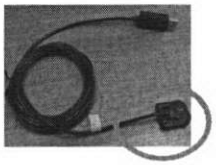
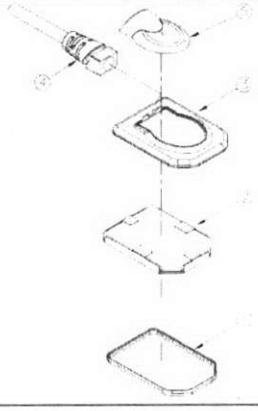
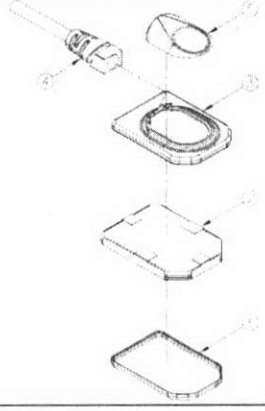
The primary difference is the size of new sensors and availability of optional image viewing software, Prora view, which is alreay cleared by FDA (K131594). As demonstrated by the technical comparison between the subject and predicate device, the difference in the physical dimension of the sensor does not present any new concerns in terms of safety and effectiveness.

1. HDI 2000 / HDI 2000A Summary

1.1 Hardware

The hardware of HDI 2000 and HDI 2000A are identical.

The shape of the top cover and case of EzSensor P (K121132) are modified without affecting the sensor performance.

Change	HDI 2000 / HDI 2000A	EzSensor P
 Sensor_ASS'Y ③ : Upper Case ⑤ : Top Cover		

1.2 Viewer Software

This device is operated using viewer software. With the identical hardware configuration, the model name is distinguished by the type of image viewing software available. The software functions include the patient information management, image capture, and viewer for captured images.

Model	**Sensor Type**	**Size** (mm)	**Viewer Software**	**Viewer Software Manufacturer**
HDI 2000	1.5	38.7 x 29.2 x 4.95	Easydent	Rayence Co., Ltd.
HDI 2000A	1.5	38.7 x 29.2 x 4.95	ProraView (K131594)	EWOO Soft
HDI 2000	2.0	42.8 x 31.5 x 4.95	Easydent	Rayence Co., Ltd.
HDI 2000A	2.0	42.8 x 31.5 x 4.95	ProraView (K131594)	EWOO Soft

Easydent is the same software used for the predicate device whereas ProraView image viewing software is a stand alone imaging viewer program with 510(k) clearance of its own. Both viewing programs have the similar functionality and performance. The main difference is the design of the user interface (UI) and new consulting simulation tool for Prora View. Prora View requires a fee based license registration for the right to use whereas EasyDent is provided to users free of charge.

The design control risk analysis for ProraView describes hazards associated with respect to SRS and SDS. All risks are mitigated and any residual risks are determined acceptable.

2.1) Difference for Easydent and ProraView

	Easydent	**ProraView**
Function	Patient View Acquisition Consultation Report	Patient View **Acquisition** Consultation Report **License**

Summary for any testing in the submission

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.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.

All test results were satisfactory.

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 that HDI 2000 / HDI 2000A is safe and effective and substantially equivalent to predicate device as described herein.

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

May 13, 2014

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

Re: K140060
Trade/Device Name: Digital Dental Intra Oral Sensor (HDI 2000, HDI 2000A)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and MUH
Dated: April 15, 2014
Received: April 18, 2014

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" (21CFR 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,

for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140060

Device Name
HDI 2000, HDI 2000A digital dental image processing system

Indications for Use *(Describe)*

HDI 2000 / HDI 2000A, 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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