September 27, 2023

Qpix Solutions Inc.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group LLC
7505 Fannin St., Suite 610
HOUSTON TX 77054

Re: K232255
Trade/Device Name: EzSensor XHD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: July 31, 2023
Received: July 31, 2023

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232255

Device Name
EzSensor XHD

Indications for Use *(Describe)*

EzSensor XHD 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.

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

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1. 510(k) Summary : K232255

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: July 27, 2023

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

Submitter's Name :	Qpix Solutions Inc
Submitter's Address:	1001 Aviation Parkway, Ste 200, Morrisville, North Carolina, USA 27560
Submitter's Telephone:	+1-919-908-6917
Contact person:	Mr. Seungman Yun / CEO / +1-919-908-6917
Official Correspondent:	Dave Kim **(**davekim@mtechgroupllc.com**)**
Address:	7505 Fannin St. Suite 610, Houston, TX 77054
Telephone:	+713-467-2607

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 XHD
Model Name:	IOS-A15IF, HDI-15DGF
Common Name:	Digital Dental Intra Oral Sensor
Regulatoin number:	21 CFR 872.1800
Classification Name :	Extraoral source X-ray system
Regulatory Class:	CL 2
Product Code:	MUH

Predicate Device :

Manufacturer	: Rayence Co., Ltd.
Device	: EzSensor Soft, EzSensor Soft i, EzSensor Bio, EzSensor Bio I, Model: 1.0, 1.5, 2.0

510(k) Number	: K151707 (Decision Date –07/19/2015)
The Regulation Number	: 21 CFR 872.1800
Classification Name	: Extraoral Source X-ray System
Regulatory Class	: CL 2
Primary Product Code	: MUH

2. Device Description

EzSensor XHD is a digital intraoral sensor which acquires digital intra-oral images. EzSensor XHD acquires intra oral 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. The ergonomic design based on human intraoral anatomy improves patient comfort. EzSensor XHD includes the software (firmware) with MODERATE level of concern.

3. Indication for use

EzSensor XHD 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

EzSensor XHD described in this 510(k) has the same indications for use and similar technical characteristics as its 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 a new sensor size were analyzed by conducting complete verification for IEC 60601-1 and drop & vibration test which included electronic shock, leakage current, etc…

While applying the stainless-steel material to the inside of the frame, soft silicon material surrounds the exterior of the USB connector to protect the sensor from 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
Manufacturer	Qpix Solutions Inc	Rayence Co., Ltd
Device name	EzSensor XHD (Model: IOS-A15IF, HDI-15DGF)	EzSensor Soft, EzSensor Soft i, EzSensor Bio, EzSensor Bio i
Feature		
510(k) number	K232255	K151707
X-ray converter	CsPbBr3	Gd2O2S:Tb
Detection type	Direct conversion	Indirect conversion
Indications for use	EzSensor XHD 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 Sensors are 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) (±10%)	Size 1.5: 41.1 x 30.4	Size “1.0”: 37.8 x 26.6 Size “1.5”: 40.8 x 30.6 Size “2.0”: 44.0 x 32.5
Sensor Thickness(mm)	6.2	5
Available Active Area size (mm)	Size 1.5: 23.98 x 33.00	Size “1.0”: 20.01 x 30.01 Size “1.5”: 23.98 x 33.00 Size “2.0”: 25.99 x 35.99
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module

Max. Resolution (lp/mm)		33.8	
Pixel Pitch(㎛)	***Full Resolution***	14.8	
DQE (6 lp/mm)	***Full Resolution***	0.204	0.144
MTF (3 lp/mm)	***Full Resolution***	0.685	0.456
Typical dose range(μGy)		Incisor & Canine : 300 ~ 500 / Molar: 400 ~ 600	
Viewer Software (option)		EzDent-I (K223820)	Easydent or EzDent-I (K150747)

6.Summary of Performance Testing

The indications for use, and application of EzSensor XHD is the same as that of the predicate device, EzSensor Soft.
EzSensor XHD is a direct conversion sensor that utilizes a photoconductor (CsPbBr3) and single crystal Silicon as the sensing means whereas EzSensor Soft, the predicate device, utilizes single crystal Silicon and fluorescent materials (Gd2O2S:Tb) as the sensing means.
The performance test results indicate that the EzSensor XHD intraoral sensor performed equally to the EzSensor Soft, the predicated device, as both sensors have the same pixel pitch, thereby providing the same maximum line-pair resolution. No additional safety risk is identified in the bench test: Non-clinical report.
Non-clinical test was performed according to FDA Guidance “Guidance for the Submissions of 510(k)’s for Solid State X- ray Imaging Devices”.

DQE, MTF, and NPS test results demonstrated that EzSensor XHD has better performance outcome than EzSensor Soft, the predicate sensor.

Electrical, mechanical, environmental safety and performance testing were performed according to IEC 60601-1:2005, AMD1:2012 (Medical electrical equipment Part 1:General requirements for basic safety and essential performance). EMC testing was conducted in accordance with standard IEC 60601-1-2:2014.

The clinical images obtained from the EzSsensor XHD and EzSensor Soft were reviewed and rated comparatively.

EzSensor XHD produces overall better definition and grayscale of bony and soft tissue images in comparison with EzSensor Soft.
In conclusion, both the proposed device and the predicate device produced radiographic images with adequate quality for intra oral diagnosis in terms of resolution and anatomic details.

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. Qpix Solutions Inc concludes EzSensor XHD is substantially equivalent to EzSensor Soft, the predicate device as described herein.