November 10, 2025

Qpix Solutions Inc
℅ Dave Kim
President
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K252570
Trade/Device Name: EzSensor HD, EzSensor UHD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: August 11, 2025
Received: October 22, 2025

Dear Dave 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiologic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252570

Device Name
EZ Sensor HD, EZ Sensor UHD

Indications for Use *(Describe)*

EzSensor HD / UHD 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.

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

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"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."

510(k) Summary
K252570

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 11, 2025

1. 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, 27560 USA
Submitter's Telephone:	+1-919-908-6917
Contact person:	Mr. Seungman Yun / CEO / +1-919-908-6917
Official Correspondent:	Mtech Group LLC Mr. Dave Kim, MBA
Address:	7505 Fannin St. Ste 610, Houston, TX 77054
Telephone:	+713-467-2607
Email:	davekim@mtechgroupllc.com

2. 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 HD, EzSensor UHD
Model Name:	IOS-U20IF, IOS-U15IF, IOS-U10IF
Common Name:	Digital Dental Intra Oral Sensor
Regulatoin number:	21 CFR 872.1800
Classification Name:	Extraoral source X-ray system
Regulatory Class:	Class 2
Product Code:	MUH

3. Predicate device

Trade Name:	X Sensor
510(k) Number :	K242778 (Decision Date –10/11/2024)
The Regulation Number:	21 CFR 872.1800
Classification Name:	Extraoral Source X-ray System
Regulatory Class :	Class 2
Primary Product Code :	MUH

4. Device Description

EzSensor HD / UHD is a digital intraoral sensor which 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 Indirect sensor systems is the speed with which images are acquired. The ergonomic design based on human intraoral anatomy improves patient comfort. EzSensor HD / UHD includes the software (firmware) with basic level of concern.

5. Indication for use

EzSensor HD / UHD 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.

6. 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.

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

Digital intraoral sensor 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 sensors 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**
Manufacturer	Qpix solutions Inc	Qpix solutions Inc
Device's name	EzSensor HD, EzSensor UHD (Model: IOS-U20IF, IOS-U15IF, IOS-U10IF)	X Sensor (Model: IOS-A15IF, HDI-15DGF)
Feature		
510(k) number	K252570	K242778
X-ray converter	CsI	CsPbBr3
Indications for use	EzSensor HD / UHD 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) (±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 1.5: 41.1 x 30.4
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 1.5: 23.98 x 33.00
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module
Max. Resolution (lp/mm)	33.8	33.8

Pixel Pitch (μm)	***Full Resolution***	14.8	14.8
DQE (6 lp/mm)	***Full Resolution***	0.318	0.278
MTF (3 lp/mm)	***Full Resolution***	0.668	0.716
Viewer Software		EzDent-i (K241114) dental imaging viewer by EWOO SOFT	EzDent-i (K241114) dental imaging viewer by EWOO SOFT

8. Summary of Performance Testing

The intended use, application of **EzSensor HD(EzSensor UHD)** is the same as that of the predicate device, **X Sensor**.

EzSensor HD(EzSensor UHD) is a Indirect conversion sensor that utilizes a photoconductor (**CsI**) and single crystal Silicon as the sensing means whereas X **Sensor**, the predicate device, utilizes a photoconductor(**CsPbBr3**) and single crystal Silicon as the sensing means.

The performance test result indicates that the **EzSensor HD(EzSensor UHD)** intra oral sensor performed equally to the **X Sensor**, 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”.

Due to differences in the utilization a photoconductor between the EzSensor(EzSensor UHD) CsI and the predicate device X Sensor CsPbBr3, there is a slight variation in EzSensor HD MTF(0.668) for X Sensor MTF(0.716). However, this difference doss not affect their practical equivalence performance.

Summary of EzSensor HD for Image Quality Test

The image quality test of EzSensor HD (Report No.: Q-20250613-01) confirmed that there were no special issues with the resolution and image quality.

DQE, MTF, and NPS test results demonstrated that **EzSensor HD(EzSensor UHD)** has equivalent performance outcome than **X Sensor**, the predicate sensor.

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

Electrical, mechanical, environmental safety and performance testing were performed according to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 (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+AMD1:2020.

The clinical images obtained from the **EzSensor HD(EzSensor UHD)** and **X Sensor** were reviewed and rated comparatively.

The image quality in terms of contrast and resolution are overall similar for the **EzSensor HD(EzSensor UHD)**, the proposed new device and **X Sensor**, the predicate device

There are no observable radiographic findings and no quality issues with intra oral diagnostic images provided by both sensors.

The proposed device produces overall better definition and grayscale of bony and soft tissue images.

The expert evaluation of the representative clinical images demonstrated that the proposed device achieved equivalent image quality to the predicate device.

9. 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 HD(EzSensor UHD)** is safe and effective and substantially equivalent to predicate device as described herein.