October 10, 2023

% Mr. Edward Park
CEO
LightenBridge LLC
4408 Tortuga Ln
McKINNEY TX 75070

Re: K230916
Trade/Device Name: WeSensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: April 3, 2023
Received: April 3, 2023

Dear Mr. Park:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230916

Device Name
WeSensor

Indications for Use *(Describe)*
The WeSensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

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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510(k) Summary – Traditional 510(k)

K230916

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

Submitter Information

Submitter Name:	PICOPACK Inc.
Address:	#106, 91, Sinilseo-ro 85beon-gil, Daedeok-gu, Daejeon 34325 Republic of Korea
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Contact Person:	Edward Park, official correspondent of Picopack Co., Ltd.
Date of submission:	April 01, 2023

Device Information

Proprietary Name(s):	WeSensor
Model Name:	F350A / G350A / F150A / G150A
Common Name:	Intraoral digital X-ray sensor
Regulation Name:	Extraoral Source X-Ray System
Product Code:	MUH
Regulation Number:	21 CFR 872.1800
Classification Panel:	Radiology
Device Class:	II

Device Description

The WeSensor is an intraoral digital x-ray sensor. It comprises three components: (1) an intraoral digital X-ray sensor which connects to a PC via a USB port; (2) WeSensor Software package; and (3) a sensor holder as an accessory.

The sensor part of WeSensor comes in four distinct models according to active area size and scintillator type: G350A, F350A, G150A, and F150A. Both 'G' models (G350A and G150A) use a scintillator made from Gadolinium Oxysulfide (Gd2O2S:Tb), and there is no filter layer in these models. Both 'F' models (F350A and F150A) use a different type of scintillator made from Thallium-doped Cesium Iodide (CsI:Tl) and Sodium Iodide (NaI:Tl). These models also include an extra filter layer in the sensor. This unique structure of the scintillator and filter layer further enhances image quality. And model 350 having a larger active area than model 150.

There is no electrical or physical connection between the sensor and the x-ray generator. Images are automatically acquired when x-rays are present in a dose which is perceptible to the sensor. An X-ray image sensor is positioned in the patient's mouth just like Intra-oral film. Digital x-

ray images are quickly displayed on the screen. Images can be optimized for viewing via imaging software, stored as image files.

PICOPACK offers technical support for this device to ensure proper operation and to answer any questions regarding the function of the device. The type of x-ray systems that integrate with the G350A/F350A/G150A/F150A are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time.

This device cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. There is no connection between the subject device and the x-ray generator. The subject device does not control the generator, it is a receiver. G350A/F350A/G150A/F150A must be connected to a PC through the standard USB 2.0 port.

The WeSensor Viewer is a software component designed to be operated within Windows Desktop environment for medical device acquisition, storage, transmission along with simple editing functions. Using Picopack's provided SDK in local settings allows users to connect this software directly to an oral sensor for X-ray image acquisition and patient image viewing. This software has moderate level of concern and this software has not been previously FDA-cleared with other similar detectors.

Primary Predicate Device

- QuickRay HD (Denterprise International, Inc., K151926)

  - Common Name: Intraoral Digital X-Ray Sensor
  - Regulation Name: Extraoral Source X-Ray System
  - Device Class: II
  - Product Code: MUH
  - Regulation Number: 21 CFR 872.1800
  - Medical Specialty: Dental
  - Review Panel: Radiology

Additional Predicate Devices

- XVD2121 Plus, XVD2530 (Shenzhen Xpectvision Technology Co., Ltd., K220277)

  - Common Name: Intraoral Digital X-Ray Sensor
  - Regulation Name: Extraoral Source X-Ray System
  - Device Class: II
  - Product Code: MUH
  - Regulation Number: 21 CFR 872.1800
  - Medical Specialty: Dental
  - Review Panel: Radiology

- EzSeonsor Classic (Rayence Co., Ltd., K153060)

  - Common Name: Digital Dental Intra Oral Sensor
  - Regulation Name: Extraoral Source X-Ray System
  - Device Class: II
  - Product Code: MUH
  - Regulation Number: 21 CFR 872.1800
  - Medical Specialty: Dental
  - Review Panel: Radiology

Indications for Use

WeSensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

Intended Use

WeSensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures. WeSensor is located in the patient's mouth and used together with a separate medical device, X-ray generator, used once for one patient, and can be used for another patient by replacing the designated protective cover after use. WeSensor should only be used by dentists.

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Comparison of Technological Characteristics with Predicate

Device Name	WESENSOR	QuickRay HD (Primary Predicate)	XVD2121 Plus, XVD2530	EzSeonsor Classic	Differences
510k number	K230916	K151926	K220277	K153060	
Manufacturer	Picopack Co., Ltd.	Denterprise International, Inc.	Shenzhen Xpectvision Technology Co., Ltd.	Rayence Co., Ltd.	
Indications for Use	The WeSensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.	QuickRay HD is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.	The digital intraoral X-ray sensors XVD2121 Plus, XVD2530 are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. Each can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.	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	Identical to K151926
Intended Use	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.	Identical
Principle of operation	X-ray (radiation) => scintillator (convert to light) => fiber optic layer (only in F type) (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)	X-ray (radiation) => scintillator (convert to light) => fiber optic layer (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)	X-ray (radiation) => Scilicon-based chip (direct imaging) => Solder bump => Readout chip (convert to digital) => PC (capture & display image)	X-ray (radiation) => scintillator (convert to light) => fiber optic layer (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)	Similar or Identical

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Device Name	WESENSOR	QuickRay HD (Primary Predicate)	XVD2121 Plus, XVD2530	EzSeonsor Classic	Differences
510k number	K230916	K151926	K220277	K153060	
Manufacturer	Picopack Co., Ltd.	Denterprise International, Inc.	Shenzhen Xpectvision Technology Co., Ltd.	Rayence Co., Ltd.	
Software - Firmware	Firmware combined on sensor electronic board	Firmware combined on sensor electronic board	Unknown	Unknown	Identical
Software - Image Management	WeSensor Viewer (Picopack, Korea)	Xray Vision (OTS package from Apteryx, USA)	XLinearVision	Easydent	Identical
Sensor technology	**F350A/F150A** : CMOS chip + optical fiber plate + CSi scintillator **G150A/G350A** : CMOS chip + CSi scintillator	CMOS chip + optical fiber plate + CSi scintillator	Scilicon-based Semiconductor + CMOS ASIC	CMOS chip + optical fiber plate + FOS scintillator (FOP + CsI)	Identical for F350A and F150A Similar for G150A and G350A
Sensor Dimension (mm)	G150A: 37.0 × 27.0 × 1.0 F150A: 37.0 × 27.0 × 1.2 G350A: 43.0 × 33.0 × 1.0 F350A: 43.0 × 33.0 × 1.2	36.8 × 25.4 × 4.4 41.9 × 30.4 × 4.4	XVD2121: 32.0 × 26.5 × 5.8 XVD2530: 38.5 × 31.5 × 6.0	Size 1.0: 36.8 × 25.4 × 4.8 Size 1.5: 39.5 × 29.2 × 4.8 Size 2.0: 42.9 × 31.3 × 4.8	Similar
Active Area	**G150A/F150A** : 30.0 mm × 21.6 mm **G350A/F350A** : 34.4 mm × 26.2 mm	600 mm² (Size 1) 884 mm² (Size 2)	XVD2121 : 20.0 mm × 19.8 mm XVD2530 : 29.5 mm × 24.6 mm	Size 1.0: 30.01 × 20.01 Size 1.5: 33.00 × 23.98 Size 2.0: 35.99 × 25.99	Similar

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Device Name	WESENSOR	QuickRay HD (Primary Predicate)	XVD2121 Plus, XVD2530	EzSeonsor Classic	Differences
510k number	K230916	K151926	K220277	K153060	
Manufacturer	Picopack Co., Ltd.	Denterprise International, Inc.	Shenzhen Xpectvision Technology Co., Ltd.	Rayence Co., Ltd.	
Number of Pixels	**G150A/F150A** : 1500 × 1080 **G350A/F350A** : 1700 × 1300	1500 × 1000 (Size 1) 1700 × 1300 (Size 2)	Unknown	**Normal Resolution Mode** Size 1.0: 1014 × 676 Size 1.5: 1115 × 810 Size 2.0: 1216 × 878 **High Resolution Mode** Size 1.0: 2028 × 1352 Size 1.5: 2230 × 1620 Size 2.0: 2462 × 1756	Similar
Lifespan CMOS	Min. 100,000 cycles	Min. 100,000 cycles	5 years	Unkown	Identical
Max. Image Resolution (lp/mm)	G150A & G350A: 14.3 F150A & F350A: 16.6	≥ 20pl/mm	7 lp/mm	UnKnown	Similar
Pixel Size	20 × 20μm	20 × 20μm	Unknown	Unknown	Identical
Gray Levels	14 bits	14 bits	16 bits	Unknown	Identical
DQE	0.464 at 0 lp/mm 0.060 at 6 lp/mm	0.45 at 0 lp/mm 0.16 at 6 lp/mm		Full Resolution : 0.38 at 6 lp/mm Binning Resolution : 0.34 at 6 lp/mm	Similar
MTF	0.594 at 3 lp/mm 0.1 at 13 lp/mm	0.65 at 3 lp/mm 0.09 at 13 lp/mm		Full Resolution : 0.642 at 3 lp/mm Binning Resolution : 0.630 at 3 lp/mm	Similar

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Device Name	WESENSOR	QuickRay HD (Primary Predicate)	XVD2121 Plus, XVD2530	EzSeonsor Classic	Differences
510k number	K230916	K151926	K220277	K153060	
Manufacturer	Picopack Co., Ltd.	Denterprise International, Inc.	Shenzhen Xpectvision Technology Co., Ltd.	Rayence Co., Ltd.	
Sensor board	All control electronics directly integrated on CMOS sensor chip.	All control electronics directly integrated on CMOS sensor chip.	All control electronics directly integrated on CMOS sensor chip.	All control electronics directly integrated on CMOS sensor chip.	Identical
Sensor shell	ABS (flammability is FV-0) (UL File No. E257054)	ABS (flammability is HB if YK-94 (UL File No. 49895))	Unknown	Silicon	Similar
Cable material and design	PVC, ETFE, copper, plug connector Diameter: ϕ3.8 ±0.3 Cable length: 2.5 meters.	PVC, ETFE, copper, plug connector, and sensor connector Diameter: ϕ3.7 ±0.3 Cable length: 2 meters.	Unknown	Unknown	Similar
Connection to imaging practice PC	USB 2.0 High-Speed	USB 2.0 High-Speed	USB 2.0 High-Speed	USB 2.0	Identical
Operating temperature	10°C to 35°C	0°C to 35°C	10°C to 40°C	10°C to 30°C	Similar
Sensor input voltage and current	5VDC (via USB connection) 0.5A Max	5VDC (via USB connection) 0.15A Max	5VDC (via USB connection) 0.25A Max	5VDC (via USB connection) 0.5A Max	Similar

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Performance Data

Sensor performance testing and software function test have been undergone for the WeSensor intraoral digital x-ray detector. The successful test results including max.image resolution, DQE, and MTF indicate that the subject device performance is comparable to or exceed those of the predicate devices. Also, clinical images were examined by Dr.Park, a qualified dentist in the state of Nevada. The results demonstrated no significant difference in diagnosing dental diseases between the subject device and the predicate device.

Electrical Safety and EMC

Non-clinical test was performed in accordance with the following international standards,

- IEC 60601-1:2012 ed.3.1
- IEC 60601-1-6 Edition 3.1 2013-10 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- ANSI AAMI IEC 62304:2006+AMD1:2015 Medical Device Software – Software Life Cycle Processes
- EN ISO 14971:2012 Medical devices - Applications of risk management to medical devices
- ANSI AAMI IEC IEC 62366:2007 Medical devices Part 1: Application of usability engineering to medical devices

Conclusion

The subject device is substantially equivalent with the predicate device in the areas of indications for use, intended use, general functions & features, principle of operation, and technological characteristics. The new device does not introduce fundamentally new scientific technology. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.