October 7, 2021

iRay Technology Taicang Ltd.
℅ Wei Pan
Registration and Regulatory Affairs Deputy Director
No. 33 Xinggang Rd. Taicang Port Economic & Technological Development Zone
Taicang, Jiangsu 215434
CHINA

Re: K212279
Trade/Device Name: Digital Intraoral X-ray Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: May 31, 2021
Received: July 20, 2021

Dear Wei Pan:

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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

The respective Form FDA 3881 is attached within this submission.

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)*
K212279

Device Name
Digital Intraoral X-Ray Imaging System

Indications for Use *(Describe)*
Digital intraoral X-ray Imaging System, models i-Sensor H1 and i-Sensor H2, are used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination, the diagnosis of structural diseases of teeth, jaws and mouth. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors.
This device is not intended for mammography and conventional photography applications.
This device is suitable for providing dental radiography imaging for both adult and pediatric.

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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510(k) Summary of Safety and Effectiveness

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. Date Prepared [21 CFR 807.92(a)(1)]

May 31, 2021

2. Submitter's Information [21 CFR 807.92(a)(1)]

Company Name:	iRay Technology Taicang Ltd.
Company Address:	No.33 Xinggang Road, Taicang Port Economic and Technological Development Zone, Jiangsu, China 215434
Contact Person:	Guo Wu
Phone:	0512-53698213
Fax:	0512-53690872
Email:	guo.wu@iraygroup.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name:	Digital Intraoral X-ray Imaging System
Common Name:	Extraoral Source X-Ray System
Model Name:	i-Sensor H1
	i-Sensor H2
Classification Name:	Extraoral Source X-Ray System
Product Code:	MUH
Regulation Number:	21 CFR 872.1800
Device Class:	Class II

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification predicates within this submission are as follows:

Manufacturer:	iRay Technology Taicang Ltd.
Trade Name:	Digital Intraoral X-ray Imaging System
Model Name:	Pluto0001X
	Pluto0002X
Product Code:	MUH
Classification Name:	Extraoral Source X-Ray System
Regulation Number:	21 CFR 872.1800
Device Class:	Class II
FDA 510 (k) #:	K210312

5. Description of the Device [21 CFR 807.92(a)(4)]

The Digital intraoral X-ray Imaging System, models i-Sensor H1 and i-Sensor H2, are the digital intra-oral sensor. It features a 20μm pixel pitch CMOS sensor with directly deposited CsI:Tl scintillator which ensures optimal resolution. An easy to use hi-speed direct USB interface enables a simple connection to a PC without need for an additional control box. The optional intra-oral software application makes it easy to acquire, enhance, analyze, view and share images from the sensor.

The major function of i-Sensor H1 and i-Sensor H2 are to convert the X-ray to digital image, with the application of high resolution X-ray imaging. This detector is the key component of intra-oral DR system, enables to complete the digitalization of the medical X-ray imaging with the intra-oral DR system software.

6. Intended Use [21 CFR 807.92(a)(5)]

6.1. Indications for use

Digital intraoral X-ray Imaging System, models i-Sensor H1 and i-Sensor H2, are used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination, the diagnosis of structural diseases of teeth, jaws and mouth. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors.

This device is not intended for mammography and conventional photography applications.

This device is suitable for providing dental radiography imaging for both adult and pediatric.

6.2. Suitable patient

This device is suitable for both adult and pediatric.

6.3. Processing of input and output

The sensor plate is direct-deposited with CsI scintillator to achieve the conversion from X-ray to visible photon. The visible photons are transformed to electron signals by diode capacitor array within CMOS panel, which are composed and processed by connecting to scanning and readout electronics, consequently to form a panel image by transmitting to PC through the user interface.

When i-Sensor H1/ i-Sensor H2 work continuously, it can automatically distinguish X-ray and output an imaging for diagnosis of disease, injury, or of any applicable health problem.

7. **Technological Characteristic [21 CFR 807.92(a)(6)]**

Item	Predicate Device: Digital Intraoral X-Ray Imaging System Pluto0001X and Pluto0002X	Proposed Device: Digital Intraoral X-Ray Imaging System i-Sensor H1 and i-Sensor H2
Model name	PlutoX sensor	i-Sensor H1 & i-Sensor H2
510(K) Number	K210312	K212279
Classification Name	Extraoral Source X-ray System	Same
Product Code	MUH	Same

Item	Predicate Device: Digital Intraoral X-Ray Imaging System Pluto0001X and Pluto0002X	Proposed Device: Digital Intraoral X-Ray Imaging System i-Sensor H1 and i-Sensor H2
Regulation Number	21 CFR 872.1800	Same
Panel	Radiology	Same
Classification:	II	Same
X-Ray Absorber (Scintillator):	CsI	Same
Installation Type:	Portable	Same
Detector structure:	CMOS Photodiode Array	Same
Dimensions:	Pluto0001X: 38.5mm×25mm×4.5mm Pluto0002X: 40mm×31mm×4.5mm	i-Sensor H1: 38.5mm×25mm×4.5mm i-Sensor H2: 40mm×31mm×4.5mm
Image Matrix Size:	1500×1000 pixels for Pluto0001X 1800×1300 pixels for Pluto0002X	1500×1000 pixels for i-Sensor H1 1800×1300 pixels for i-Sensor H2
Pixel Pitch:	20μm	Same
Effective Imaging Area:	30mm×20mm for Pluto0001X; 36mm×26mm for Pluto0002X;	30mm×20mm for i-Sensor H1; 36mm×26mm for i-Sensor H2;
Spatial resolution	16lp/mm	Same
Modulation Transfer Function (MTF)	0.1 at 12.5lp/mm	Same
Power Consumption:	5V DC, 400mA	5V DC, 500mA
Communications:	USB 2.0	Same
Cooling:	Air cooling	Same
Protection against matter/Water	IP68	Same
Protection against shock	Type BF applied part	Same
Operation:	Temperature: 10 to 35℃ Humidity: 20 to 90% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters	Same

Item	Predicate Device: Digital Intraoral X-Ray Imaging System Pluto0001X and Pluto0002X	Proposed Device: Digital Intraoral X-Ray Imaging System i-Sensor H1 and i-Sensor H2
Storage and Transportation: （detector）	Temperature: -10 to 55℃ Humidity: 10 to 95% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Same
Software	iRayDR	Ai-Dental

8. **System requirements to operate with other radiographic system components**

1) Recommended Generator Specification:

Energy range: 55~100kV

mA range: 10~1000mA (depending on the generator power)

ms range: 10~6300ms to produce 0.1~1000mAs (depending on the generator power)

Note: To our best knowledge, the i-Sensor H1 & i-Sensor H2 are compatible with the X-ray generators with the specifications described above.

2) Application Program Interface (API) for system integration manufacturer

Peripheral hardware: the i-Sensor H1 & i-Sensor H2 connected via USB2.0 communication.

Operating System:	Windows® 7 or above
CPU:	Intel® Core 2
Memory:	2 GB or above
Hard Disk:	320 GB or above
USB port:	4 high-speed USB 2.0 ports

3) X-ray exposure mode

The AED mode can connect X-ray signal in the i-Sensor H1 & i-Sensor H2. Once there is X-ray generator exposure exist, the inner trigger module will detect the X-ray radiation and output signal to the intraoral sensor. Until the exposure finished, the sensor will receive a signal which represent the end of exposure from the inner trigger module and begin to acquire the image.

9. Nonclinical study

1) Electrical Safety and EMC testing:

Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 and IEC60601-2-65 were performed, and EMC testing was also conducted in accordance with IEC 60601-1-2. All test results are meet the standard requirements.

2) Biological Evaluation:

Although there is a single-use protective sheeth prior to each use, the materials of the intra-oral sensor enclosure which may contact patient's oral mucosa have been evaluated with the ISO10993-1. And the evaluation results and test result assured the safety the same as the predicate device.

The sensor position frame is evaluate and assured the safety the same as the predicate device.

3) Nonclinical Considerations:

According to the *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*, the non-clinical studies have been performed and the results have shown that the i-Sensor H1 & i-Sensor H2 are substantially equivalent to the predicate devices on the Market (K210312),The below applicable items are evaluated:

Dose to output signal transfer function, Signal to noise ratio, uniformity, Defect, Minimum triggering dose rate, Modulation transfer function (MTF), Spatial resolution, Low contrast resolution and Image Acquisition time.

According to the Guidance for the *Content of Premarket Submissions for Software Contained in Medical Device*s and the *Content of Premarket Submissions for*

Management of Cybersecurity in Medical Devices, the software Ai-Dental classifies the hazards, defines requirements specification and design specification, all the specification pass all the test cases and complies the intended design specification. According to the *Guidance for the Pediatric Information for X-ray Imaging Device Premarket Notifications*, the pediatric capabilities and labeling requirements were considered during the design and development process, the related information is shown in the User's manual.

4) Clinical Consideration:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterizes all performance aspects of the device based on well-established scientific and engineering principles.

10. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Guilin Woodpecker Medical Instrument Co., Ltd. Concludes that i-Sensor H1 & i-Sensor H2 are substantially equivalent to predicate device with regards to safety and effectiveness.