October 20, 2023

iRay Imaging Technology (Haining) Limited
℅ Junjie Qian
Registration & Regulation Affairs Engineer
3rd floor, Building 1, No. 2, Caohejing Rd.
Haining, Jiangsu 314499
CHINA

Re: K230998
Trade/Device Name: Digital Wireless Intraoral X-Ray Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: February 13, 2023
Received: April 7, 2023

Dear Junjie Qian:

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 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)*
K230998

Device Name
Digital Wireless Intraoral X-Ray Sensor

Indications for Use *(Describe)*
The Digital Wireless Intraoral X-Ray Sensor (Pluto0002XW) is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. 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.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

February 13, 2023

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

Company Name:	iRay Imaging Technology (Haining) Limited
Company Address:	3rd floor, Building 1, No. 2, Caohejing RD., Haining 314499, China
Contact Person:	Junjie Qian
Phone:	0573-87399739
Email:	Junjie.qian@iraygroup.com

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

Trade Name:	Digital Wireless Intraoral X-Ray Sensor
Common Name:	Extraoral Source X-Ray System
Model Name:	Pluto0002XW
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 Co. Ltd.
Trade Name: Model	PlutoX Digital Intraoral X-Ray Imaging System
Name: Product	Pluto0002X
Code:	MUH
Regulation Number:	21 CFR 872.1800
Classification Name:	Extraoral Source X-ray System
FDA 510 (k) #:	K210312
Device Class:	Class II

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

The Pluto0002XW Digital Wireless Intraoral X-Ray Sensor (Hereinafter referred to as Pluto0002XW) contains the digital intra-oral sensor. It features a 20μm pixel pitch CMOS sensor with directly deposited CsI:Tl scintillator which ensures optimal resolution.

The major function of the Pluto0002XW is to convert the X-ray to digital image, with the application of high resolution X-ray imaging. Pluto0002XW 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.

The iRay intra-oral software (iRayDR) is part of the system, it is used to acquire, enhance, analyze, view and share images from the sensor. Based on how the operation of the software associated with device function affects the patient or operator, and the effect may be direct or indirect, we hereby certify that the level of concern for our product, use the software 1.0207 version is Moderate. iRayDR has been cleared with the predicate device（K210312）

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

6.1 Indications for Use

The Digital Wireless Intraoral X-Ray Sensor (Pluto0002XW) is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. 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, but not suitable for pregnant women.

6.3. Processing of input and output

The sensor plate of Pluto0002XW is direct-deposited with CsI(Cesium Iodide) 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 Pluto0002XW works 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 Dental Intra Oral Sensor	Proposed Device: Digital Wireless Intraoral X-Ray Sensor
510(K) Number	K210312	K230998
Classification Name	Extraoral Source X-ray System	Same
Product Code	MUH	Same
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
Indications for Use	The Digital Intra-Oral X-Ray Imaging System (Pluto0001X/Pluto0002X) is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. The product is expected to be used in hospitals and clinics, operated and used by	Same

Item	Predicate Device: Digital Dental Intra Oral Sensor	Proposed Device: Digital Wireless Intraoral X-Ray Sensor
	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.	
CMOS sensor dimension:	Pluto0002X： 40mm×31mm×4.5mm	45mm×31.6mm×4.5mm
Image Matrix Size:	Pluto0002X：1800×1300 pixels	Same
Pixel Pitch:	20μm	Same
Effective Imaging Area:	Pluto0002X：36mm×26mm	Same
Spatial resolution	16lp/mm	Same
Modulation Transfer Function (MTF)	0.1 at 12.5lp/mm	Same
Power Consumption:	5V DC, 400mA	≤3.5W
Communication	USB 2.0	Wireless IEEE 802.11
power supply mode	USB 2.0	Internal battery
Cooling:	Air cooling	Same
IP grade	COMS Sensor: IP68 USB box: IP20	CMOS Sensor: IP68 Handle: IP44 Charging Base: IP44
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	Temperature: 10 to 35℃ Humidity: 5 to 90% (Non-Condensing) Atmospheric pressure: 700 to 1060 hPa Altitude: Max. 3000 meters
Storage and Transportation:	Temperature: -10 to 55℃ Humidity: 10 to 95%	Temperature: -20 to 55℃ Humidity: 5 to 95%

Item	Predicate Device: Digital Dental Intra Oral Sensor	Proposed Device: Digital Wireless Intraoral X-Ray Sensor
	(Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	(Non-Condensing) Atmospheric pressure: 700 to 1060 hPa Altitude: Max. 3000 meters
Software	iRayDR	Same

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 Pluto0002XW is compatible with the X-ray generator with the specifications described above.

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

Peripheral hardware: Pluto0002XW connected via Wireless communication.

Operating System:	Windows 7 or above 32/64bit
CPU:	Intel Core i5 3.6G
Memory:	8G DDR3
Hard Disk:	640 G

3) X-ray exposure mode

The AED mode can connect X-ray signal in the Pluto0002XW. 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) Wireless testing

Wireless functionality and wireless coexistence testing in accordance with ANSI IEEE C63.27-2017 was performed. All test results are meet the standard requirements.

3) Cybersecurity testing

Cybersecurity threat modeling, risk assessment, and controls and testing were performed to comply with requirements specified in section 524B(b)(2) of the Federal Food, Drug, and Cosmetics Act to provide a reasonable assurance that the subject device with its wireless capabilities are cybersecure

4) Biological Evaluation:

Although there is a single-use protective sheath 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.

5) Nonclinical Considerations:

Main modification from the predicate device is power supply mode, communication, and IP grade

The non-clinical studies have been performed and the results have shown that sections of the non-clinical consideration mentioned in the 'Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices' are substantially equivalent to the non-consideration of predicate devices on the Market (Pluto0002X, K210312).

6) Clinical Consideration:

Intended use, fundamental scientific technology, regulatory requirement, non-clinical performance, labeling, quality-assurance program, keep the same with those of predicate device. Additionally, as mentioned in clinical considerations in '*Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*', clinical consideration may not necessary for changes in the wireless functionality if non-clinical information is sufficient to support the substantial equivalence.

10. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, iRay Imaging Technology (Haining) Limited. concludes that Pluto0002XW is substantially equivalent to predicate device with regards to safety and effectiveness.