April 21, 2023

iRay Imaging Technology (Haining) Limited
℅ Jeffrey Wu
Registration & Regulation Affairs Engineer
No. 2, Caohejing RD., Haining 314499, Jiaxing
Zhejiang, P.R.China
Haining, Zhejiang 314499
CHINA

Re: K230811
Trade/Device Name: Digital 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: March 20, 2023
Received: March 24, 2023

Dear Jeffrey Wu:

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 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)*

K230811

Device Name
Digital Intraoral X-Ray Sensor

Indications for Use *(Describe)*

Used in conjunction with a pulsed dental X-ray machine, the CS 6200 is intended for medical institutions to perform static digital X-ray imaging facilitating the diagnosis of the teeth, jaw, mouth, and other structural diseases.

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.

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

March 05, 2023

2. Submitters Information [21 CFR 807.92(a)(1)]

Company Name: iRay Imaging Technology (Haining) Limited

Company Address: No. 2, Caohejing RD., Haining 314499, Jiaxing, Zhejiang, P.R.China

Contact Person: Jeffrey Wu

Phone: 86-21-50720539

Fax: 86-21-50720561

Email: guo.wu@iraygroup.com

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

Trade Name: Digital Intraoral X-Ray Sensor

Common Name: Extraoral Source X-Ray System

Model Name: CS 6200

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: PlutoX Digital Intraoral X-Ray Imaging System

Model Name: Pluto0001X, Pluto0002X

Product Code: MUH

Classification Name: Extraoral Source X-Ray System

FDA 510 (k) #: K210312

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

The CS 6200 is a USB-driven digital intraoral X-ray sensor based on CMOS technology that is specially designed for acquiring real-time high-quality dental diagnostic images. Image data acquired from the device can be transmitted via a USB 2.0 port to a workstation for display and processing.

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

6.1. Indications for use

Used in conjunction with a pulsed dental X-ray machine, the CS 6200 is intended for medical institutions to perform static digital X-ray imaging facilitating the diagnosis of the teeth, jaw, mouth, and other structural diseases.

6.2. Suitable patient

The device is intended for use by trained and qualified dentists, dental technicians, and maintenance personnel.

It is not suitable for mammography and dynamic imaging photography. Do not use it on pregnant women.

6.3. Processing of input and output

When sensor 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 Intraoral X-Ray Imaging System	Proposed Device: Digital Intraoral X-Ray Sensor
Model Name:	Pluto0001X Pluto0002X	CS 6200
510(K) Number:	K210312	To be determined
Classification	Extraoral Source X-ray System	Same

Item	Predicate Device: Digital Intraoral X-Ray Imaging System	Proposed Device: Digital Intraoral X-Ray Sensor
Name:		
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
Degree of protection against electrical shock:	Type BF	Same
Detector structure:	CMOS Photodiode Array	Same
Power Consumption:	DC 5V, 400mA	Same
Dimensions:	Pluto000lX: 38.5mm✕25mm✕4.5mm Pluto0002X: 40mm✕31mm✕4.5mm	23.4mm✕33.6mm✕4.5mm
Image Matrix Size:	1500 ✕ 1000 pixels for Pluto0001X 1800 ✕ 1300 pixels for Pluto0002X	900 ✕ 1200 pixels
Pixel Pitch:	20μm	Same
Effective Imaging Area:	30mm ✕ 20mm for Pluto0001X; 36mm ✕ 26mm for Pluto0002X;	18mm ✕ 24mm
ADC Digitization:	16 bit	Same
Spatial Resolution:	Max 25lp/mm	Max 25lp/mm
Modulation Transfer Function (MTF):	10% at 12.5 lp/mm	10% at 8.0 lp/mm
Communications:	USB 2.0	Same
Cooling:	Air cooling	Same
Protection against matter/Water	IP68	Same
Operation:	Temperature: 10 to 35℃	Temperature: 10 to 35℃

Item	Predicate Device: Digital Intraoral X-Ray Imaging System	Proposed Device: Digital Intraoral X-Ray Sensor
	Humidity: 20 to 90% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters	Humidity: 5 to 95% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters
Storage and Transportation:	Temperature: -10 °C ~ 55 °C Humidity: 10% ~ 95% (Non-Condensing) Atmospheric pressure: 70kPa~106kPa Altitude: Max. 3000 meters	Temperature: -20 °C ~ 55 °C Humidity: 5% ~ 95% (Non-Condensing) Atmospheric pressure: 70kPa~106kPa Altitude: Max. 3000 meters
Software:	iRayDR	No accompanying software

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 sensor is compatible with the X-ray generators with the specifications described above. If you have any questions regarding the compatibility issue for other generators, please contact your distributor or iRay's service office.

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

Peripheral hardware: CS 6200 connected via USB 2.0 communication.

Operating System:	Windows 7 64bit, or even higher
CPU:	Inter(R) Celeron N3450 frequency≥1.5GHz, or even higher
Memory:	8G DDR3 or higher
Hard Disk:	500 G or higher
Port:	USB 2.0

Display setting: 1278 ✕ 768

3) X-ray exposure mode

The AED module can connect X-ray signal in the CS 6200. Once there is X-ray generator exposure exist, the inner trigger module will detect the X-ray radiation and output signal to the detector. Until the exposure finished, the detector 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.

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 CS 6200 are substantially equivalent to the predicate devices on the Market (K210312):

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.

In addition, the propose device does not include software, so it will not affect the safety and effectiveness.

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

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, manufacturer concludes that CS 6200 is substantially equivalent to predicate device with regards to safety and effectiveness.