January 17, 2023

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

Re: K223010
Trade/Device Name: Portable X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: December 19, 2022
Received: December 19, 2022

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,

Lu Jiang
2023.01.17
21:51:54
-05'00'

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)*
K223010

Device Name
Portable X-ray System

Indications for Use *(Describe)*
The Portable X-ray System is used as a portable, extra oral x-ray source for producing diagnostic x-ray images using conventional film, PSP (phosphor plates) or digital sensors. It is intended for adult and pediatric patients.
This equipment is available only to trained and qualified dentist or dental technician.

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

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

   Sep. 18, 2022

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

Company Name:	iRay Technology Taicang Ltd.
Company Address:	No.33 Xinggang Rd., Taicang Port Economic & Technological Development Zone
Contact Person:	Wei Pan
Phone:	+86 21 50720560
Fax:	+86 21 50720561
Email:	wei.pan@iraygroup.com

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

Trade Name:	Portable X-ray System
Common Name:	Extraoral Source X-ray System
Model Name:	Canis014D07
Classification Name:	Extraoral Source X-ray System
Product Code:	EHD
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:	GENORAY Co., Ltd.
Trade Name:	PORT-X IV
Model Name:	PORT-X IV
Product Code:	EHD
Classification Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Device Class:	Class II
FDA 510 (k) #:	K172810

The identification of reference device within this submission are as follows:

Manufacturer:	Aribex, Inc.
Trade Name:	NOMAD Pro X-ray system
Model Name:	NOMAD Pro
Product Code:	EHD
Classification Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Device Class:	Class II
FDA 510 (k) #:	K081664

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

The portable X-Ray system, Canis014D07, is intended to be used by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intraoral image receptors. The images presented in the product screen are for preview purposes only, not for imaging diagnosis. It also includes accessories, which are battery, recharging unit and hand switch.

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

6.1. Indications for use

The portable X-Ray system is used as a portable, extra oral x-ray source for producing diagnostic x-ray images using conventional film, PSP (phosphor plates) or digital sensors. It is intended for adult and pediatric patients. This equipment is available only to trained and qualified dentist or dental technician.

6.2. Suitable patient

The Canis014D07 is intended for adult and pediatric patients.

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

Item	Predicate Device: PORT-X IV	Reference Device: NOMAD Pro	Proposed Device: Canis014D07
Model name	PORT-X IV	NOMAD Pro	Canis014D07
510(K) Number	K172810	K081664	K223010
Classification Name	Extraoral Source X-ray System	Same	Same
Product Code	EHD	Same	Same

Item	Predicate Device: PORT-X IV	Reference Device：NOMAD Pro	Proposed Device: Canis014D07
Regulation Number	21 CFR 872.1800	Same	Same
Panel	Dental	Same	Same
Classification:	II	Same	Same
Installation Type:	Portable	handheld	Portable
Indications for use	PORT-X IV is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.	The NOMAD Pro X-ray System is intended to be used by trained dentists and dental technicians as an extraoral X-ray source for producing diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects	The Portable X-ray System is used as a portable, extra oral x-ray source for producing diagnostic x-ray images using conventional film, PSP (phosphor plates) or digital sensors. It is intended for adult and pediatric patients. This equipment is available only to trained and qualified dentist or dental technician.
X-ray Monoblock	Tube Voltage : 70 kV Tube Current : 2 mA Stationary Anode Focus : 0.4 mm Target Angle : 12.5° Total Filtration : 2.2 mmAl (Inherent Filtration : 1.0 mmAl; Additional Filtration : 1.2 mmAl)	Tube Voltage : 60 kV fixed Tube Current : 2.5 mA Stationary Anode Focus : 0.4 mm Target Angle : 12.5° Total Filtration : 1.5mmAl	Tube Voltage : 70 kV Tube Current : 2 mA Stationary Anode Focus : 0.4 mm Target Angle : 12.5° Total Filtration : 3.1 mmAl (Inherent Filtration : 1.0 mmAl; Additional Filtration : 2.1 mmAl)
Exposure controller	Exposure Time : 0.05~1.6 sec.	Exposure Time : 0.02~1 sec.	Exposure Time : 0.04~2 sec.
Battery	Rechargeable lithium battery	Same	Same
Display	LCD panel Dispaly	Same	Same
Dimensions	(140 × 173 × 254)mm	(280×165×296)mm	（197×139×240）mm
Weight	1.6 kg	2.5kg	2.2kg

Item	Predicate Device: PORT-X IV	Reference Device: NOMAD Pro	Proposed Device: Canis014D07
Cooling:	Air cooling	Same	Same
Protection against matter/Water	IPX0	Same	Same
Operation:	Temperature: 10 to 35℃ Humidity: 30 to 85% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters	Temperature: -5 to 40℃ Humidity: 10 to 80% (Non-Condensing)	Temperature: 10 to 40℃ Humidity: 10 to 90% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters
Storage and Transportation:（detector）	Temperature: -15 to 55℃ Humidity: 10 to 90% (Non-Condensing) Atmospheric pressure: 50 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 to 60℃ Humidity: 95% (Non-Condensing)	Temperature: -20 °C ~ 55 °C Humidity: 5% ~ 95% (Non-Condensing) Atmospheric pressure: 70kPa~106kPa Altitude: Max. 3000 meters
Software	VXvue	Embedded software	iRayDR 1.0407

8. Safety, EMC and Performance data comparison to Predicate device

8.1 Safety, EMC and Performance data

Canis014D07 complies with industry standards such as IEC 60601-1 Series and 21 CFR 1020.30 and 21CFR 1020.31 to minimize electrical, mechanical and radiation hazards.

a) Electrical, mechanical, environmental safety and performance testing which are mentioned in the standard ANSI ES:60601-1, IEC 60601-1-3 and IEC 60601-2-65 were performed.

b) EMC testing was conducted in accordance with standard IEC 60601-1-2.

c) Performance testing performed according to FDA 21 CFR 1020.30, 21 CFR 1020.31 standards, Software Validation, nonclinical Evaluation. All test

results were fulfill the requirements.

8.2 - Summary of Performance Testing

The performance test for the subject device (Canis014D07) and the predicate device (PORT-X IV, K172810) are identical in the indications for use, patient population, intended operation environment, and electrical safety. They are similar in technical specification. The differences between the proposed device and the predicate device will not raise any new risk to affect safety or effectiveness.

9. Nonclinical study

9.1 Electrical Safety and EMC Summary

The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:

a) ANSI AAMI ES60601-1:2005 + A1:2012 + A2:2021
b) IEC 60601-1-3:2008 + A1:2013 + A2:2021
c) IEC 60601-2-65:2012 + A1:2017
d) IEC 60601-1-2:2014

9.2 Bench Testing Summary

The verification test results showed compliance with the above standards. Validation was performed for overall operation by taking and reviewing test images. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the primary predicate.

9.3 Summary of Clinical Tests:

The subject of this premarket submission, the test images were reviewed by a professional with adequate qualifications, and that the images were of diagnostic quality did not require more clinical studies.

10. FDA Guidance Documents Utilized

a) *Format for Traditional and Abbreviated 510(k)s Guidance* issued on September 13, 2019.
b) *Radio Frequency Wireless Technology in Medical Devices*
c) *Guidance for Medical X-ray Imaging Devices Conformance with IEC Standards*

d) *Guidance for the Content of Premakret Submissions for Software Contained in Medical Devices*, issued Nov 28, 2017

e) *Pediatric Information for X-ray Imaging Device Premarket Notifications*, issued November 28, 2017

a) *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014

11. 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, the manufacturer, iRay Imaging Technology (Haining) Limited concludes that Canis014D07 is substantially equivalent to predicate device with regards to safety and effectiveness.