Rolence Enterprise, Inc.
% Sterling Cheng
General Manager
18-3 Lane 231 Pu Chung Rd., Chungli
Taoyuan, 32083
TAIWAN

March 16, 2018

Re: K172928
Trade/Device Name: XR-01 Portable X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: February 22, 2018
Received: February 23, 2018

Dear Sterling Cheng:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172928

Device Name
XR-01 Portable X-Ray System

Indications for Use *(Describe)*
The XR-01 Portable 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 child subjects

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date 510(k) Summary prepared	2018/2/1
Submitter Name	Rolence Enterprise Inc. Address: 18-3 Lane 231 Pu Chung Rd., Chungli, Taoyuan, Taiwan
Contact Person	Jui-Ya Lai Regulatory Affairs Quality Assurance Associate Manager
Telephone	+886-3-4631999
FAX	+886-3-4631997

Device Information	
Type of 510(k) Submission	Traditional
Trade or Proprietary Name	XR-01 Portable X-Ray System
Common or Usual Name	Portable X-ray System
Regulation Name	Extraoral source x-ray system
Regulation Number	872.1800
Product Code	EHD
Class of Device	Class II
Panel	Radiology

1. **Comparison with predicate devices:**

		Subject Device	**Primary Predicate Device**	**Reference Devices**	
Device Name		XR-01 Portable X-Ray System	Nomad Pro Intraoral X-Ray system	Port-X II	DX-3000 Portable X-Ray System
Regulation Number		872.1800	872.1800	872.1800	872.1800
Regulation Name		Extraoral source x-ray system	Extraoral source x-ray system	Extraoral source x-ray system	Extraoral source x-ray system
Regulatory Class		II	II	II	II
Primary Product Code		EHD	EHD	EHD	MUH
Applicant Name		Rolence Enterprise Inc.	Aribex Inc.	Genoray Co., Ltd.	Dexcowin Co., Ltd.
510(k) Number		-	K081664	K063121	K133007
INTENDED USE		All four systems are intended as extraoral X-ray sources to be used with intraoral image receptors for diagnostic imaging by dentist or dental technicians.			
Mechanical	**Size (mm)**	174 x 178 x 257	266.7 x 133.35 x 304.8	197 x 147 x 145.5	139 x 163.5 x 66.5

	Source to skin distance	200 mm	210 mm	100 mm	> 100 mm (fixed by cone)
	X-ray field Size	60 mm round	60 mm round	70 mm round	50 mm round
	User Interface	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image receptor type and tooth selection icon on control panel.	Up-down buttons for exposure time selection, with timer display. Additionally, several user-selectable preset times with patient size, image receptor type, and tooth selection icons on an LCD display.	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size and tooth selection icons on an LCD display.	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size and tooth selection icons on an LCD display.
	Backscatter radiation protection	Available as optional accessory	171.45 mm dia. Pb-filled acrylic plastic scatter shield	None	Available as optional accessory
	Exposure Switch	Exposure button at front body	Trigger on Handset	Exposure button at x-ray control panel	Exposure button at front body
	Tube head mounting	Handheld or on a tripod	Handheld	Handheld or on a tripod	Handheld
Electrical	**Energy source**	Rechargeable 25.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 16.8 V DC Lithium Polymer battery pack
	Exposure time	0.01 – 2.00 seconds in 0.01 steps	0.02 - 1.00 seconds in 0.01 increments	0.01 – 2.0 seconds in 46 steps	0.05 – 1.35 seconds in 0.01 steps
	mA	2 mA fixed	2.5 mA fixed	2 mA fixed	2 mA
	kVp	60 kVp fixed	60 kVp fixed	60 kVp fixed	60 kvp
	Waveform	Constant Potential (DC)	Constant Potential (DC)	Constant Potential (DC)	Constant Potential (DC)
	Duty Cycle	1:30	1:60	N/A	1:60
Applied Standards		IEC 60601-1,	IEC/EN	UL/IEC	21 CFR

	EN 60601-1-2, IEC 60601-1-3, IEC 60601-2-65, IEC 62133 21 CFR 1020.30, 21 CFR 1020.31	60601-1, EN 60601-1-2, IEC 60601-1-3, IEC 60601-2-7, 21 CFR 1020.30, 21 CFR 1020.31	60601-1, IEC 60601-1-2 IEC 60601-2-7, 21 CFR 1020.30, 21 CFR 1020.31	1020.30, 21 CFR 1020.31

Device Description
XR-01, a portable X-ray system is mainly designed for dental diagnosis via X-ray exposure with intraoral image receptors, supplied with 25.2 V DC rechargeable Li-ion polymer battery. The portable X-ray system consist of an x-ray generator with an x-ray tube, device controller, beam limiting device, AC-DC power supply, charging unit and optional back scatter shield.

Indication for Use
The XR-01 Portable 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 child subjects.

Performance Testing
Subject device XR-01 complies with safety and performance standards which are in accordance with 21 CFR 1020.30 and 31. Performance test validate that accuracy, reproducibility, deviation and linearity of technical factors such as tube voltage, tube current and exposure time is meet the criteria. Safety tests in terms of HVL, leakage, x-ray field size meet Federal standard requirements.

Standards and Guidance Documents

Electrical Safety and EMC Standards
- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- EN 60601-1-2:2015
- IEC 60601-1-3:2008 (Second Edition) + A1:2013 for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012
- IEC 60601-1-6:2010 (Third Edition) + A1:2013
- IEC 60601-2-65:2012 (First Edition) for use in conjunction with IEC 60601-1:2005 (Third edition)

Battery Safety Standards
- IEC 62133:2012 (Second Edition)

Usability Standards
- IEC 62366: 2007 (First Edition) + A1: 2014

Radiation Control
- 21 CFR 1020.30
- 21 CFR 1020.31

Guidance

- Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use
- How to Prepare a Special 510(k)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Pediatric Information for X-ray Imaging Device Premarket Notifications
- Applying Human Factors and Usability Engineering to Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical
- Devices
- Refuse to Accept Policy for 510(k)s
- eCopy Program for Medical Device Submissions

Conclusion

The subject device and predicate devices have same intended use and principle of operation. Also, both of them met Federal regulations 21 CFR Part 1020.30, 1020.31 and international medical device safety standard. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Rolence Enterprise Inc. concludes that the Portable X-Ray System (XR-01) is safe and effective and substantially equivalent to predicate devices as described herein.