July 13, 2023

Ningbo Runyes Medical Instrument Co., Ltd.
℅ W. Lee Strong
Quality Systems Manager
510K FDA Inc.
156 E Granada Blvd.
ORMOND BEACH FL 32176

Re: K231449
Trade/Device Name: Portable X-ray System Model Ray98(P)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: May 16, 2023
Received: May 18, 2023

Dear W. Lee Strong:

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
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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)*
K231449

Device Name
Portable X-ray System Model Ray98(P)

Indications for Use *(Describe)*
The device is a diagnostic X-ray system which 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 intra-oral receptors. Its use is intended for both adults and pediatric 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.

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510(k) Summary

Submitter/Applicant

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Date Prepared: July 13, 2023

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Device Classification

Trade/Model Names:	Portable X-ray System Model Ray98(P)
Common Name:	Portable X-ray System
Regulation Name:	Extra-oral Source X-ray System
Regulation Number:	21 CFR 872.1800
Primary Product Code:	EHD
Classification Name:	Unit, X-ray, Extraoral with Timer
Regulatory Class:	II

510k Review Panel: Dental

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K180561
Applicant:	Denterprise International, Inc.
Date Cleared:	April 4, 2018
Trade Name:	MobileX Portable X-ray System (Model T-100).
Regulation Name:	Extra-oral Source X-ray System
Regulation Number:	21 CFR 872.1800
Primary Product Code:	EHD
Classification Name:	Unit, X-ray, Extraoral with Timer
Regulatory Class:	II
510k Review Panel:	Dental

Indications for Use

The device is a diagnostic X-ray system which 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 intra-oral receptors. Its use is intended for both adults and pediatric subjects.

Intended Use

Intended as extraoral x-ray source to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.

Device Description

The Ray98(P) by Ningbo Runyes Medical Instrument Co., Ltd., is a portable x-ray device. The technology of this device was originally developed in Korea more than a decade ago and global production is still concentrated in that country.

The subject device is designed for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structure by exposing an x-ray image receptor to ionizing radiation. The x-ray source, a tube, is located inside the portable device. All three conventional types of intraoral receptors can be used with this device—analog x-ray film, digital phosphorous plates, and digital x-ray sensors.

This device is used in general dentistry and is supplied with an internal timer to control the duration of the x-ray source to the patient. The portable x-ray device is a choice model to assist doctors with special need patients, nursing home patients and patients in the office that cannot be easily moved, as well as other special situations. The choice of an x-ray generator is a matter of functional utility in the dental operatory and personal preference by the medical professional.

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

Device Characteristic	Subject Device Portable X-ray System Model Ray98(P)	Predicate Device Mobile-X Portable X-ray System (K180561)	Comparison
510(k) Owner	Ningbo Runyes Medical Instrument Co., Ltd. (China)	Denterprise International, Inc. (USA)	NA
Classification & Product Code	872.1800; EHD	872.1800; EHD	Similar
Intended Use	Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	Similar
Indication for Use	The device is a diagnostic X-ray system which 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 intra-oral receptors. Its use is intended for both adults and pediatric subjects.	The device is a diagnostic X-ray system, which 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 intra-oral receptors. Its use is intended for both adults and pediatric subjects.	Similar
Size	5.75” x 6.0” x 9.5”	6.5” x 6.0” x 10.5”	**Difference of design, size**
Source to Skin Distance	20.5 cm ±0.5cm	20.5 cm	**Difference .5 cm**
Cone diameter	6.0 cm ±0.5cm	6.0 cm	**Difference ±0.5cm**

Device Characteristic	Subject Device Portable X-ray System Model Ray98(P)	Predicate Device Mobile-X Portable X-ray System (K180561)	Comparison
User interface	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, image-receptor type, and tooth selection icons on an LCD display.	**Difference; subject device does not set image-receptor type**
Exposure switch	Exposure button at front cover on right hand side or remote switch.	Exposure button at front cover on right hand side or remote switch.	Similar
Electrical Information			
Exposure time	0.04 ~ 2.0 seconds in fixed increments: 0.04s, 0.05s, 0.06s, 0.08s, 0.10s, 0.12s, 0.16s, 0.20s, 0.25s, 0.32s, 0.40s, 0.50s, 0.63s, 0.80s, 1.00s, 1.25s, 1.60s, 2.00s	0.01 ~ 1.3 seconds in 0.01 or 0.05 increments	**Difference; subject device has higher exposure time limits and fixed increments**
Time accuracy	± (10% +1 ms)	± (10% +1 ms)	Similar
mA	2mA	2mA	Similar
kVp	70kVp	70kVp	Similar
Waveform	Constant Potential (DC)	Constant Potential (DC)	Similar
Total Filtration	1.5mmAl	1.5mmAl	Similar
Half-Value Layer (HVL)	1.6mm Al	1.5mm Al	**Difference; subject device has higher HVL**
X-ray Focal Spot	0.4mm	0.4mm	Similar

Device Characteristic	Subject Device Portable X-ray System Model Ray98(P)	Predicate Device Mobile-X Portable X-ray System (K180561)	Comparison
Average Number of 0.5s Exposures with Fully Charged Battery	500	400	**Difference; subject device has higher average exposures**
Performance standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304 IEC 62366 ISO 14971	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304 IEC 62366 ISO 14971	Similar

The above comparison shows the subject and predicate devices have substantially similar technological characteristics. Differences show up in the shape, size, design of the device and those are in cm and mm measurements of slight difference. The differences of the device are minor and do not raise new issues of safety and effectiveness.

Non-Clinical Performance Data

The following performance testing was completed on the subject device in support of the substantial equivalence determination of the predicate device.

- Electrical Safety and EMC
- Software Validation
- Usability
- Clinical Evaluation
- Risk Assessment

- All tests were performed in accordance with IEC and ISO standards and tests are recognized by FDA.
- None of the standards were adapted for application to the device under review.
- No deviations from the standards were applied.
- No differences exist between the tested device and the device to be marketed.
- Conformity with all standards was determined by the device manufacturer, Ningbo Runyes Ltd., Korea.

- Electrical test performed by KCTL, Inc. Laboratories, Inc., Korea.

Specific Guidance Document

The Guidance document: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* applies to this device. Details of this guidance are provided within the Software Validation Report.

Labels

The labels on the device show that this device conforms to the following:

21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products,
21 CFR 1020.30: Diagnostic x-ray systems and their major components,
21 CFR 1020.31: Radiographic Equipment

Substantial Equivalence

The above comparison chart shows the subject and predicate devices have similar technological characteristics.

Both devices have:

- Similar function and are used in similar environments.
- The same indications for use and the same intended use.
- Similar manufacturing process and similar technological characteristics.
- Both devices have completed similar IEC and ISO standardized testing listed in the comparison chart shown above.

Conclusion

The subject and predicate device have the same indications for use, the same intended use and similar technological characteristics. The Portable X-ray System Model Ray98(P) performs similar functions, in a similar environment as the predicate device. Portable X-ray System Model Ray98(P) uses similar technology as the predicate device, based on well-known technology. Portable X-ray System Model Ray98(P) is as safe and effective as the predicate device. We believe the subject device does not introduce any new safety concerns and is substantially equivalent to the predicate device. In conclusion, the subject device, Portable X-ray System Model Ray98(P), is at least as safe and effective as the predicate device and warrants a finding of substantial equivalence to the legally marketed device.