NANORAY Co., Ltd.
℅ Sanglok Lee
Manager
Wise Company Inc.
#303, 142, Gasan digital 1-ro
Geumcheon-gu, Seoul 08507
REPUBLIC OF KOREA

December 28, 2020

Re: K201800
Trade/Device Name: Portable Dental X-ray (NR-F350, CS 2400P, CS 2300P, R2 Port-X)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: November 20, 2020
Received: November 23, 2020

Dear Sanglok Lee:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201800

Device Name
Portable Dental X-Ray (NR-F350, CS 2400P, CS 2300P, R2 Port-X)

Indications for Use *(Describe)*
The Portable Dental X-Ray (Model: NP-350E) is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

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.

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NANORAY

510(k) Summary

The assigned 510(k) Number: K201800

01. Date of Submission: December 24, 2020

02. Applicant

Company name: NANORAY Co., Ltd.
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03. Submission Correspondent

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04. Subject Device

Proprietary Name: Portable Dental X-ray (NR-F350, CS 2400P, CS 2300P, R2 Port-X)
Model Name: NP-350E
Classification & Regulation Name: Extraoral source x-ray system
Device Class: Class II
Regulation Number: 21 CFR 872.1800
Product Code: EHD

05. Indication for Use

The Portable Dental X-Ray (Model: NP-350E) is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

06. Predicate Devices

Predicate Device

- 510(k) Number: K173319
- Device Name: KaVo NOMAD Pro 2 Handheld X-ray System
- Manufacturer: Aribex
- Regulation Number: 21 CFR 872.1800
- Regulation Name: Extraoral source x-ray system
- Regulatory Class: II
- Product Code: EHD

Reference Device

- 510(k) Number: K152859
- Device Name: Portable X-ray System (Model: MINIX-V / MINIX-S)
- Manufacturer: Digimed Co., Ltd.
- Regulation Number: 21 CFR 872.1800
- Regulation Name: Extraoral source x-ray system
- Regulatory Class: II
- Product Code: EHD

07. Device Description

Portable Dental X-ray (Model: NP-350E) is a super capacitor-operated, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-rays images utilizing either film or digital imaging techniques. The Portable Dental X-ray Device is designed for use in a dental office. It can also be used in other similar environments (orthodontic office, general practitioner's office, hospital ward, etc.) where appropriate safeguards are implemented. The device uses a rechargeable super capacitor to allow for the use of the Portable Dental X-ray Device where transportation or use of other x-ray devices might be prohibitive due to the other device's size and/or lack of mobility.

The Portable Dental X-ray Device is an X-ray device with a DC generator. The handheld device features a main unit (tube head), charger(cradle), and charger AC/DC power supply. The power is supplied by a rechargeable super capacitor built into a device. This facilitates portability of the device. A beam-limiting cone is incorporated within the device. Internal and external shielding provide sufficient radiation protection to allow the clinician to remain in the operatory with the patient.

To make the system as simple as possible for the operator, Portable Dental X-ray Device uses a fixed tube voltage of 70kV and a fixed tube current of 3.5mA. The only operator-adjustable parameter is the exposure time. This adjustment can be quickly accomplished through the user-friendly control panel.

Control buttons, display, and a trigger provide the primary operator interface. Exposures settings can be selected and displayed. Voltage (70 kV) and current (3.5 mA) are fixed with the exposure time varying based on patient type, detector type, and anatomical feature. Exposures can be completed using the trigger. The device can be used with three detector types: film, digital imaging intraoral sensors, and phosphor plates.

08. Principle of Operation / Mechanism of Action:

The Portable Dental X-ray (Model: NP-350E) is used like any other extraoral dental Xray source for intraoral application.
An image receptor, such as film, is placed in the patient's oral cavity behind the teeth.
The device is powered on, and the appropriate exposure time is set by the operator.
The operator should follow appropriate instructions to ensure proper alignment of the X-ray beam to the receptor, and proper positioning of the receptor in the patient's mouth.
To prevent inadvertent exposure to X-rays, the operator must first press the lock/unlock button to enable and then ready the device.
X-rays are initiated by pulling and holding the trigger on the handle for the duration of the exposure.
The system has numerous alarms and alerts to communicate with the operator.

09. Non-Clinical Test Data:

Testing was performed in accordance with the following international standards:
- IEC 60601-1: 2005/ A1:2012 “Medical electrical equipment Part 1: General requirements for basic safety and essential performance”
- IEC 60601-1-2:2014 “Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests”
- IEC 60601-1-3:2008/A1:2013 “Medical electromagnetic equipment- Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment”
- IEC 60601-1-6:2010/A1:2013 “Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability”
- IEC 60601-2-65:2012/ A1:2017 “Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment”
- IEC 62304:2006/A1:2015 “Medical device software – Software life cycle processes”
- IEC 62366-1:2015 “Medical devices – Application of usability engineering to medical devices”

10. Technological Characteristics:

Portable Dental X-ray (NR-F350, CS 2400P, CS 2300P, R2 Port-X) is substantially equivalent in virtually all aspects to the commercially available predicate device (K173319) and reference device (K152859) with respect to technical characteristics, intended use and principle of operation.

Additionally, Energy Source, of the KaVo NOMAD Pro 2 Handheld X-ray System relative to the predicate device and Portable X-ray System (Model: MINIX-V) relative to the reference device are same or very similar and, in the estimation of the manufacturer, do not raise new questions of safety and effectiveness relative to the predicate device.

Table. Characteristics Comparison of Subject and Predicate Device

	Subject device	Predicate device	Reference device
Property name	Portable Dental X-ray Device	KaVo NOMAD Pro 2 Handheld X-Ray System	Portable X-ray System (Model: MINIX-V / MINIX-S)
510(k) Number	Not assigned	K173319	K152859
Product Code	EHD	EHD	EHD
Picture			
Indication for use	The Portable Dental X-Ray (Model: NP-350E) is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray	The KaVo NOMAD Pro 2 Handheld Xray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray	The Device is a diagnostic X-ray system, which is intended to be used by trained and dental technicians as an extra-oral X-ray source for producing diagnostic X-ray images using intra-oral image receptors. Its use is

		images using intraoral image receptors.	images using intraoral image receptors.	intended for both adults and pediatric subjects.
Technical characteristic	Size: Body	10.2” (L) x 10.1” (H) x 5.4” (W)	11"L x 10.5"H x 5.5"W	4.8” (W) x 8.7”(D) x 5.3”(H)
	Weight	4.2 lbs	6.0 lbs.	4.3 lbs.
	Source to skin distance	20 cm	21 cm	20cm
	Cone diameter	8 cm	6 cm	5.5 cm
	Energy Source	14.5 VDC (Super capacitor), 10EA	Rechargeable 21.6 V DC Li-ion battery core pack	Rechargeable 22.2 V DC Lithium Polymer battery pack
	Exposure Time range	0.06 - 1.0 second	0.02 - 1.0 seconds in 0.01 increments	0.01~2.0 seconds in 0.01 increments
	mA	3.5mA	2.5 mA fixed	2 mA fixed
	kVp	70kV	60 kVp fixed	70 kV fixed (MINIX V)
Electrical Safety Standards		IEC 60601-1:2005/AMD1:2012	AAMI ES60601-1:2005/(R)2012 And A1:2012	IEC 60601-1
EMI Standards		IEC 60601-1-2:2014	IEC60601-1-2 Ed. 4	IEC60601-1-2
Performance Standard		IEC60601- 1-3:2008/AMD1:32013 IEC60601-2-65:2012/AMD1:2017	21 CFR 1020.30, 1020.31; IEC60601- 1-3; IEC60601-2-65	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65

11. Conclusion

Based on a comparison of indications for use, technological characteristics and performance data, the subject device, Portable Dental X-Ray (NR-F350, CS 2400P, CS 2300P, R2 Port-X) is deemed to be substantially equivalent to the predicate device.