May 27, 2026

PDX Co., Ltd.
℅ Lee Strong
Quality Manager
Strong Systems, Inc.
803 John Anderson Dr.
ORMOND BEACH, FL

Re: K260367
Trade/Device Name: Portable Dental X-ray System Model PDX nova
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: February 1, 2026
Received: April 24, 2026

Dear 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

GABRIELA M. RODAL -S Digitally signed by GABRIELA M. RODAL -S for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260367

Please provide the device trade name(s).

Portable Dental X-ray System Model PDX nova

Please provide your Indications for Use below.

PDX nova is a portable dental X-ray system that captures radiographic images for dental diagnosis using intra-oral imaging receptors. Only trained and qualified dental practitioner or radiologist shall use PDX nova to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K260367
PDX nova
510(k) Summary

Submitter

PDX Co., Ltd.
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Anyang-si, Gyeonggi-do 14957, Republic of Korea

Tel: +82-(0)32-8068-7717
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Contact: Hyuntaek Shim, Quality Manager
Date: January 26, 2025

Device Classification

Trade Names:	Portable Dental X-ray System Model PDX nova
Common name:	Portable X-ray System
Regulation Name:	Extra-oral Source X-ray System
Regulation Number:	21 CFR 872.1800
Product code:	EHD
Common Name:	Unit, X-ray, Extraoral with Timer
Regulatory Class:	II
510k Review Panel:	Radiology
Submission Type:	510(k)

Predicate Device

The following predicate is a legally marketed, post-amendment device:

510(k) Number	K221233
Submitters:	ECOTRON Co., Ltd
Date Cleared:	June 27, 2022
Device Name:	DT-703
Regulation Name:	Extra-oral Source X-ray
Regulation Number:	21 CFR 872.1800
Product Code:	EHD
Common Name:	Unit, X-ray, Extraoral with Timer
Regulatory Class:	II
510k Review Panel:	Radiology
Submission Type:	510(k)

Device Description

PDX nova is a handheld x-ray device 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 handheld device. The device is intended to be used with compatible intraoral image receptors.

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 choice of an x-ray generator is a matter of functional utility in the dental operatory and personal preference by the medical professional.

Indications for Use

PDX nova is a portable dental X-ray system that captures radiographic images for dental diagnosis using intra-oral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use PDX nova to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

Comparison of Characteristics with Predicate

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

Characteristic	PDX nova (Subject Device)	ECOTRON DT-703 (K221233)	Comparison
Indications for Use	PDX nova is a portable dental X-ray system that captures radiographic images for dental diagnosis using intra-oral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use PDX nova to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.	The DT-703 is a portable dental X-ray system that captures radiographic images for dental diagnosis using intra-oral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use DT-703 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.	Same
Classification & Product Code	872.1800; EHD	872.1800; EHD	Same
Size: Body	370 x 322 x 176 mm	259(L) x 277(H) x Ø165 mm (10”L x 11”H x 6.5”W)	Difference of design
Weight	2.6 kg (5.72 lbs)	1.6 kg (3.5 lbs)	Higher weight
Energy Source	Rechargeable 14.8 VDC, 1,500 mAh Li-Po battery pack Battery Charger Input: 100-240 VAC 50/60 Hz, 1.5A Output: 16.8 VDC 3.0 A.	Rechargeable 22.2 VDC, 1,000 mAh Li-Po battery pack Battery Charger Input: 100-240 VAC 50/60 Hz, 0.4A Output: 25.5 VDC 0.9 A.	Similar

User Interface	Up and down push buttons for exposure time LCD display	Left and right push keys for exposure time LCD display	Difference of design

Characteristic	PDX nova (Subject Device)	ECOTRON DT-703 (K221233)	Comparison
Exposure times	0.1 – 0.5 sec (0.01 sec. steps)	0.02 – 0.5 sec (0.01 sec. steps)	Higher minimum, same steps
kVp	70 kVp fixed	70 kVp fixed	Same
mA	3 mA fixed	3 mA fixed	Same
Focal Spot Size	0.4 mm	0.3 mm	Lower precision
Tube	D-041(CANON)	CEI OX/70-3	Different manufacturer
Total Filtration	1.5 mmAl	1.5 mmAl	Same
Source to Skin Distance (SSD)	200 mm	200 mm	Same
Electrical Safety Standards	IEC 60601-1:2005/ A2:2020	IEC 60601-1:2005 / A1:2012	Similar standards, different editions
EMI Standards	IEC 60601-1-2:2014/ A1:2020	IEC60601-1-2: 2014	Similar standards, different editions
Performance Standards	21 CFR 1020.30, 1020.31 IEC 60601-1-3:2008/ A2:2021 IEC 60601-2-65:2012/ A2:2021	21 CFR 1020.30, 1020.31; IEC60601-1-3;2013 IEC60601-2-65:2012	Similar standards, different editions

The above comparison shows the subject and predicate devices have substantially similar technological characteristics. The exposure time is similar when comparing the subject device to the predicted device. The differences of the device are minor and do not raise new issues of safety and effectiveness.

Substantial Equivalence Discussion

The subject and predicate are both Handheld/Portable X-ray Systems intended for dentist or dental hygienists as an extra-oral x-ray source for producing diagnostic x-ray images.

As shown in the comparison table above…

- Both devices have the same classification and product code.
- Both devices have similar indications for use and intended use.
- Both devices have equivalent power source of 70kVp and 3mA.
- Both devices have the same backscatter radiation protection shield and cone that are permanently attached.

Safety and effectiveness of the PDX nova device was further documented by the following:

- *Cybersecurity…* in accordance with guidance 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions' (21 CFR Part 820).
- *Software…*the software validation report is included in the submission conforming to IEC 62304.
- *Risk Management…*the risk management report was completed conforming to ISO 14971.
- *EMC and Electrical…*these test reports conform to IEC 60601-1 and 60601-1-2 standards.
- *Performance Test…*the performance test reports are for specifications and usability, conforming to IEC 60601-2-65, 60601-1-3, 60601-1-6 and 62366-1 standards.

Specific Guidance Document

There are three FDA Specific Guidance Documents associated with the device: *Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use.* This submission utilized this guidance to develop this device to ensure the safety of this device for both the operators and the patients. The Guidance document: *"Content of Premarket Submissions for Device Software Functions"* and *"Pediatric Information for X-ray Imaging Device Premarket Notifications"*. 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

Performance Testing

Performance testing was conducted to support the device's indications for use and demonstrate substantial equivalence including:

1. Tests based on consensus industry standards confirmed the performance capabilities of the subject device.

2. Results from both bench and clinical testing confirmed diagnostic image quality substantially equivalent to the predicate device

Conclusion

The comparison analysis and performance test results demonstrate the subject device is at least as safe and effective as the legally marketed predicate. The technological differences between the subject device and the predicate device do not raise new questions of safety and effectiveness. The PDX nova subject device is therefore substantially equivalent to the ECOTRON DT-703 predicate device and thus warrants clearance from FDA for marketing activities in the United States.