

K260367 Portable Dental X-ray System Model PDX novaMay 27, 2026
112 days to decisionK260367 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k260367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Feb 4, 2026
Decision date	May 27, 2026
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	PDX Co., Ltd.
Location	Anyang-Si, Gyeonggi-Do, CN
Contact	Hyuntaek Shim
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Strong Systems, Inc.
Contact	Lee Strong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260367/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026