FDA 510(k) Premarket Notification

K252909 Diagnostic X-Ray Equipment Model POCT22

CLEARED

Feb 3, 2026
144 days to decision

K252909 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k252909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Sep 12, 2025
Decision date	Feb 3, 2026
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ningbo Runyes Medical Instrument Co., Ltd.**
Location	Ningbo Zhejiang, CN
Contact	Weiqiong Fang
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**510K FDA, Inc.**
Contact	Lee Strong

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