

**K252909 Diagnostic X-Ray Equipment Model POCT22**Feb 3, 2026  
144 days to decisionK252909 · 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	<b>Ningbo Runyes Medical Instrument Co., Ltd.</b>
Location	Ningbo Zhejiang, CN
Contact	Weiqiong Fang
510(k) history	2 submissions · 2 cleared · 2023-2026

**REGULATORY CONSULTANT**

---

Consulting firm	<b>510K FDA, Inc.</b>
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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252909/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026