

**K250954 DRX-Evolution Plus X-ray System, DRX-Compass
Mobile X-ray System, Lux HD 35 detector, Lux HD 43 detector**Jan 20, 2026
298 days to decisionK250954 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k250954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 28, 2025
Decision date	Jan 20, 2026
Days to decision	298 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carestream Health
Location	Rochester, NY, US
Contact	Gina Maiolo
Website	http://www.carestream.com/default.aspx?LangType=1033
510(k) history	5 submissions · 5 cleared · 2017-2026

Carestream Health is a worldwide provider of X-ray imaging systems and precision coating services. The company is headquartered in Rochester, US. Carestream has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. The company's regulatory track record spans from 2017 to 2026, with its most recent clearance in 2026 demonstrating continued active development and market engagement. The company specializes in digital radiography systems and detectors for medical imaging applications. Product lines include mobile X-ray systems...