

K213568 DRX-Rise Mobile X-ray SystemMar 23, 2022
134 days to decisionK213568 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k213568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Nov 9, 2021
Decision date	Mar 23, 2022
Days to decision	134 days
Third-party review	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 syste...

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