

# K253185 Lux HD Detectors, DRX-LC Detector, DRX-Revolution Mobile X-Ray System

Mar 11, 2026  
166 days to decision

K253185 · Product code: IZL · Radiology  
Source: <https://www.510kdatabase.net/k253185/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Sep 26, 2025
Decision date	Mar 11, 2026
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Carestream Health</b>
Location	Rochester, NY, US
Contact	Gina Maiolo
Website	<a href="http://www.carestream.com/default.aspx?LangType=1033">http://www.carestream.com/default.aspx?LangType=1033</a>
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...