

**K203159 Lux 35 Detector**Dec 2, 2020  
40 days to decisionK203159 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k203159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Oct 23, 2020
Decision date	Dec 2, 2020
Days to decision	40 days
Third-party review	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 syste...

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