

K243556 Lux HD 35 Detector (Lux HD 35)Mar 18, 2025
120 days to decisionK243556 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k243556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 18, 2024
Decision date	Mar 18, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Lux HD 43 Detector (Lux HD 43)

APPLICANT

Company	Iray Imaging Technology (Haining) Limited
Location	Haining, CN
Contact	Junjie Qian
510(k) history	4 submissions · 4 cleared · 2023-2025

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