

K250665 SKR 3000Jun 17, 2025
104 days to decisionK250665 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k250665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Mar 5, 2025
Decision date	Jun 17, 2025
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Konica Minolta, Inc.
Location	New York, NY, US
Contact	Makoto Sumi
Website	http://www.konicaminolta.com
510(k) history	25 submissions · 25 cleared · 2014-2025

Konica Minolta, Inc. is a global imaging and technology company with a manufacturing facility in New York, US. The company develops advanced diagnostic and imaging solutions for healthcare and industrial applications. Konica Minolta has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company specializes exclusively in Radiology devices, establishing a focused regulatory portfolio. Its FDA 510(k) clearance history spans from 2014 to 2025, with recent clearances demonstrating continued active development and market engagement...

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Device record: <https://www.510kdatabase.net/k250665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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