FDA 510(k) Premarket Notification

K241319 SKR 3000

CLEARED

Nov 21, 2024
195 days to decision

K241319 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k241319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 10, 2024
Decision date	Nov 21, 2024
Days to decision	195 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...

REGULATORY CONSULTANT

Consulting firm	**Konica Minolta Healthcare Americas, Inc.**
Contact	Jan Maniscalco

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov