FDA 510(k) Premarket Notification

K213908 SKR 3000

CLEARED

Jan 31, 2022
48 days to decision

K213908 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k213908/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Dec 14, 2021
Decision date	Jan 31, 2022
Days to decision	48 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	Tsutomu Fukui
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