

K191645 SKR 4000Aug 16, 2019
58 days to decisionK191645 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k191645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jun 19, 2019
Decision date	Aug 16, 2019
Days to decision	58 days
Third-party review	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...
