FDA 510(k) Premarket Notification

K182431 Konicaminolta DI-X1

CLEARED

Nov 26, 2018
81 days to decision

K182431 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k182431/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 6, 2018
Decision date	Nov 26, 2018
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

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...