FDA 510(k) Premarket Notification

# K162504 SKR 3000

**CLEARED**

Oct 3, 2016
26 days to decision

K162504 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k162504/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Sep 7, 2016 |
| Decision date | Oct 3, 2016 |
| Days to decision | 26 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Konica Minolta, Inc.** |
| Location | New York, NY, US |
| Contact | TSUTOMU FUKUO |
| 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...