

K134002 6MP COLOR LCD MONITOR, RADIFORCE RX650Jan 31, 2014
35 days to decisionK134002 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k134002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 27, 2013
Decision date	Jan 31, 2014
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eizo Corporation
Location	Hakusan, Ishikawa, JP
Contact	TOSHIMINE HIRAKI
Website	http://www.eizo.com/
510(k) history	29 submissions · 29 cleared · 2013-2025

Eizo Corporation is a global visual display manufacturer specializing in medical imaging solutions. The company operates with a manufacturing facility in Hakusan, Ishikawa, Japan, and serves healthcare, industrial, and professional markets worldwide. Eizo has established a strong regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2013. Radiology devices represent the dominant focus, accounting for 93% of all submissions. The company remains actively engaged in regulatory submissions, wit...
