

**K153354 3MP Color LCD Monitor, RadiForce RX350**Jan 12, 2016  
53 days to decisionK153354 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k153354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Nov 20, 2015
Decision date	Jan 12, 2016
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eizo Corporation</b>
Location	Hakusan, Ishikawa, JP
Contact	Hiroaki Hashimoto
Website	<a href="http://www.eizo.com/">http://www.eizo.com/</a>
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...

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