

K162497 5MP Monochrome LCD Monitor, RadiForce GX550, GX550-ARSep 19, 2016
12 days to decisionK162497 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k162497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Sep 7, 2016
Decision date	Sep 19, 2016
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eizo Corporation
Location	Hakusan, Ishikawa, JP
Contact	Hiroaki Hashimoto
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...

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