

K170949 RadiForce MX315WApr 27, 2017
27 days to decisionK170949 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k170949/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Mar 31, 2017
Decision date	Apr 27, 2017
Days to decision	27 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...
