

K211491 RadiForce RX370Jul 12, 2021
60 days to decisionK211491 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k211491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Display, Diagnostic Radiology (PGY)
Date received	May 13, 2021
Decision date	Jul 12, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	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...