

K243221 RadiForce RX570Nov 27, 2024
51 days to decisionK243221 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k243221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Oct 7, 2024
Decision date	Nov 27, 2024
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RadiForce RX570-AR

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...