

**K180961 RadiForce MX194**May 10, 2018  
28 days to decisionK180961 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k180961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Apr 12, 2018
Decision date	May 10, 2018
Days to decision	28 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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