

K190153 RadiForce MX216Mar 8, 2019
37 days to decisionK190153 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k190153/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Display, Diagnostic Radiology (PGY) |
| Date received | Jan 30, 2019 |
| Decision date | Mar 8, 2019 |
| Days to decision | 37 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...
