

**K241441 RadiForce RX670**Jul 16, 2024  
55 days to decisionK241441 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k241441/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Abbreviated                         |
| Device classification | Display, Diagnostic Radiology (PGY) |
| Date received         | May 22, 2024                        |
| Decision date         | Jul 16, 2024                        |
| Days to decision      | 55 days                             |
| Third-party review    | No                                  |
| Combination product   | No                                  |
| PCCP authorized       | No                                  |
| Summary / Statement   | Summary                             |
| Other names           | RadiForce RX670-AR                  |

**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...