

**K231066 CuratOR EX3242-FD**Dec 18, 2023  
248 days to decisionK231066 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k231066/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 14, 2023
Decision date	Dec 18, 2023
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	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...