

**K242983 CROMA Electrosurgical Generator (PRD-EMR-050)**Feb 5, 2025  
132 days to decisionK242983 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242983/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 26, 2024
Decision date	Feb 5, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Creo Medical, Ltd.</b>
Location	Chepstow, GB
Contact	Diane Davis
510(k) history	10 submissions · 9 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242983/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026