

**K915339 GEN-X 800/300**Jan 9, 1992  
50 days to decisionK915339 · Product code: **IZO** · Radiology  
Source: <https://www.510kdatabase.net/k915339/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, High-voltage, X-ray, Diagnostic (IZO)
Date received	Nov 20, 1991
Decision date	Jan 9, 1992
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Swissray Finatech, Inc.</b>
Location	Mobile, AL, US
Contact	MICHAEL SCOTT
510(k) history	3 submissions · 3 cleared · 1991-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915339/> 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 21, 2026