

**K914301 GEN-X 800/800**Oct 30, 1991  
35 days to decisionK914301 · Product code: **IZO** · Radiology  
Source: <https://www.510kdatabase.net/k914301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, High-voltage, X-ray, Diagnostic (IZO)
Date received	Sep 25, 1991
Decision date	Oct 30, 1991
Days to decision	35 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 W 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/k914301/> 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