FDA 510(k) Premarket Notification

K915339 GEN-X 800/300

CLEARED

Jan 9, 1992
50 days to decision

K915339 · Product code: **IZO** · Radiology
Source: https://www.510kdatabase.net/k915339/

SUBMISSION DETAILS

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

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