FDA 510(k) Premarket Notification

K914301 GEN-X 800/800

CLEARED

Oct 30, 1991
35 days to decision

K914301 · Product code: **IZO** · Radiology
Source: https://www.510kdatabase.net/k914301/

SUBMISSION DETAILS

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

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