

**K953582 HFX350, 30KW, 300MA, 1 OR 3 PHASE
RADIOGRAPHIC & FLUOROSCOPIC X-RAY GENERATOR**

Sep 26, 1995
56 days to decision

K953582 · Product code: **IZO** · Radiology
Source: <https://www.510kdatabase.net/k953582/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, High-voltage, X-ray, Diagnostic (IZO)
Date received	Aug 1, 1995
Decision date	Sep 26, 1995
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Varian Canada, Inc.
Location	Canada L7g 2j4, CA
Contact	ROBERT A D'ALVES
510(k) history	7 submissions · 7 cleared · 1991-1995

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Device record: <https://www.510kdatabase.net/k953582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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