

K950037 N 800 HFFeb 15, 1995
42 days to decisionK950037 · Product code: **IZO** · Radiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, High-voltage, X-ray, Diagnostic (IZO)
Date received	Jan 4, 1995
Decision date	Feb 15, 1995
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Oldelft Corp. of America
Location	Fairfax, VA, US
Contact	CHARLES PATTIE
510(k) history	9 submissions · 9 cleared · 1989-1998

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