

K003945 OPDIMAFeb 2, 2001
43 days to decisionK003945 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k003945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 21, 2000
Decision date	Feb 2, 2001
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	PRAVEEN NADKARNI
510(k) history	778 submissions · 778 cleared · 1980-2026

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