

**K941353 MAM-CH22S MAMMOGRAPHY SYSTEM WITH
OPTIONAL MAMMOGUIDE STERIODACTIC BIOPSY SYSTEM**Mar 31, 1995
375 days to decisionK941353 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k941353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Mar 21, 1994
Decision date	Mar 31, 1995
Days to decision	375 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elscint, Inc.
Location	Mchenry, IL, US
Contact	ROCHELLE M SOBEL
510(k) history	94 submissions · 94 cleared · 1981-1998

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