

K915748 AVIVA MAMMOGRAPHIC X-RAY SYSTEMFeb 4, 1992
43 days to decisionK915748 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k915748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 23, 1991
Decision date	Feb 4, 1992
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915748/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026