FDA 510(k) Premarket Notification

K930282 AVIVA F22/MAM-CH22 W/OPTIONAL CYTOGUIDE BIOPSY SYS

CLEARED

Aug 23, 1993
214 days to decision

K930282 · Product code: **IZH** · Radiology
Source: https://www.510kdatabase.net/k930282/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jan 21, 1993
Decision date	Aug 23, 1993
Days to decision	214 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