

K904953 PLANMED SOPHIEApr 18, 1991
164 days to decisionK904953 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k904953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Nov 5, 1990
Decision date	Apr 18, 1991
Days to decision	164 days
Third-party review	No

APPLICANT

Company	Planmeca USA, Inc.
Location	Mchenry, IL, US
Contact	MATTI SPOLANDER
510(k) history	13 submissions · 13 cleared · 1984-2011

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