

K983659 PLANMED SOPHIE & PLANNED SOPHIE CLASSICNov 16, 1998
28 days to decisionK983659 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k983659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Mammographic (IZH)
Date received	Oct 19, 1998
Decision date	Nov 16, 1998
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Planned OY
Location	Helsinki, FI
Contact	LARS MORING
510(k) history	20 submissions · 20 cleared · 1992-2025

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