

K010116 PLANMED SOPHIE, PLANMED SOPHIE CLASSICMar 15, 2001
58 days to decisionK010116 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k010116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jan 16, 2001
Decision date	Mar 15, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Planmed OY
Location	Helsinki, FI
Contact	BOB PIENKOWSKI
510(k) history	20 submissions · 20 cleared · 1992-2025

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