

**K042671 PLANMED SOPHIE NUANCE CLASSIC**Nov 19, 2004  
51 days to decisionK042671 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k042671/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Sep 29, 2004
Decision date	Nov 19, 2004
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042671/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026