

**K962105 PLANNED SOPHIED CLASSIC**Feb 5, 1997  
250 days to decisionK962105 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k962105/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	May 31, 1996
Decision date	Feb 5, 1997
Days to decision	250 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Planned OY</b>
Location	Helsinki, FI
Contact	LARS MORING
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/k962105/> 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