

**K905748 MAMEX DC AMI SL12/MG15**Mar 7, 1991  
71 days to decisionK905748 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k905748/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 26, 1990
Decision date	Mar 7, 1991
Days to decision	71 days
Third-party review	No

**APPLICANT**

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Company	<b>Soredex, Inc.</b>
Location	Sf-00511 Helsinki Finland, FI
Contact	ENSIO KOSKENNURMI
510(k) history	1 submissions · 1 cleared · 1991-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905748/>; 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 21, 2026