

**K123995 MICRODOSE SI**Feb 1, 2013  
37 days to decisionK123995 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k123995/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Dec 26, 2012
Decision date	Feb 1, 2013
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Digital Mammography Sweden AB</b>
Location	Solna, SE
Contact	GUSTAV LINS
510(k) history	3 submissions · 3 cleared · 2012-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123995/> 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 17, 2026