

K130704 MICRODOSE SIDec 13, 2013
273 days to decisionK130704 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k130704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Mar 15, 2013
Decision date	Dec 13, 2013
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130704/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026