FDA 510(k) Premarket Notification

K130704 MICRODOSE SI

CLEARED

Dec 13, 2013
273 days to decision

K130704 · 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