FDA 510(k) Premarket Notification

K111324 CR MAMMOGRAPHY SYSTEM WITH DX-M DIGITIZER

CLEARED

Dec 22, 2011
225 days to decision

K111324 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k111324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	May 11, 2011
Decision date	Dec 22, 2011
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Agfa Healthcare N.V.**
Location	Mortsel, BE
Contact	PHIL CUSCUNA
510(k) history	27 submissions · 27 cleared · 2009-2025