FDA 510(k) Premarket Notification

K111361 PLANMED NUANCE EXCEL

CLEARED

Sep 23, 2011
130 days to decision

K111361 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k111361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	May 16, 2011
Decision date	Sep 23, 2011
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Planmeca USA, Inc.**
Location	Mchenry, IL, US
Contact	BOB PIENKOWSKI
510(k) history	13 submissions · 13 cleared · 1984-2011