

**K111361 PLANMED NUANCE EXCEL**Sep 23, 2011  
130 days to decisionK111361 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k111361/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111361/> 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