

**K121963 PLANMED NUANCE DIGIGUIDE**Nov 21, 2012  
139 days to decisionK121963 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k121963/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jul 5, 2012
Decision date	Nov 21, 2012
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Planmed OY</b>
Location	Helsinki, FI
Contact	LARS MORING
510(k) history	20 submissions · 20 cleared · 1992-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121963/> 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 14, 2026