

**K163328 Planned Clarity**Dec 28, 2017  
395 days to decisionK163328 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k163328/>**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	Nov 28, 2016
Decision date	Dec 28, 2017
Days to decision	395 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Planned OY</b>
Location	Helsinki, FI
Contact	Lars Moring
510(k) history	20 submissions · 20 cleared · 1992-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163328/> 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