

**K121772 ALLURA 3D-RA REL 6, 3D ROADMAP REL 1, MR-CT  
ROADMAP REL 1**Mar 21, 2013  
279 days to decisionK121772 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k121772/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 15, 2012
Decision date	Mar 21, 2013
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems Nederland B.V.</b>
Location	Best, NL
Contact	FRANS JACOBS
510(k) history	103 submissions · 102 cleared · 2005-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121772/> 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 15, 2026