

K161839 2D Quantitative AnalysisJul 29, 2016
24 days to decisionK161839 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k161839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 5, 2016
Decision date	Jul 29, 2016
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederland B.V.
Location	Best, NL
Contact	JEANETTE BECKER
510(k) history	103 submissions · 102 cleared · 2005-2026

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