

K140138 HEARTNAVIGATOR RELEASE 2.0Jun 10, 2014
139 days to decisionK140138 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k140138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 22, 2014
Decision date	Jun 10, 2014
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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