

**K181966 SmartPerfusion**Aug 17, 2018  
25 days to decisionK181966 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k181966/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 23, 2018
Decision date	Aug 17, 2018
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems Nederlands B.V.</b>
Location	Best, NL
Contact	Chandrika Srinivasan
510(k) history	8 submissions · 8 cleared · 2015-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181966/> 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