

K181830 Azurion R2.0Aug 2, 2018
24 days to decisionK181830 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k181830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 9, 2018
Decision date	Aug 2, 2018
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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