

**K254186 Azurion R3.1**Jan 16, 2026  
24 days to decisionK254186 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k254186/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 23, 2025
Decision date	Jan 16, 2026
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems B.V.</b>
Location	Best, NL
Contact	Supriya Dalvi
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254186/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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