

K251827 Azurion R3.1Oct 24, 2025
133 days to decisionK251827 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k251827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 13, 2025
Decision date	Oct 24, 2025
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems B.V.
Location	Best, NL
Contact	Rithika Gidijala
510(k) history	2 submissions · 2 cleared · 2025-2026

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