

K200917 Azurion R2.1May 1, 2020
25 days to decisionK200917 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k200917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Apr 6, 2020
Decision date	May 1, 2020
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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