

K232420 Zenition 30Feb 16, 2024
189 days to decisionK232420 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k232420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 11, 2023
Decision date	Feb 16, 2024
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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