

K212813 Zenition 70Oct 1, 2021
28 days to decisionK212813 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k212813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 3, 2021
Decision date	Oct 1, 2021
Days to decision	28 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	Swapnil Sharadkumar Jain
510(k) history	103 submissions · 102 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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