

K183040 Zenition 70Dec 6, 2018
35 days to decisionK183040 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k183040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 1, 2018
Decision date	Dec 6, 2018
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183040/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026