

K243446 3DXRFeb 25, 2025
111 days to decisionK243446 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k243446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 6, 2024
Decision date	Feb 25, 2025
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems SCS
Location	Buc Cedex, FR
Contact	Ning WEN
510(k) history	37 submissions · 37 cleared · 2008-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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