

K243646 Ziehm Solo FDMar 17, 2025
111 days to decisionK243646 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k243646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 26, 2024
Decision date	Mar 17, 2025
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ziehm Imaging GmbH
Location	Orlando, FL, US
Contact	Cornelia Schildbach
510(k) history	18 submissions · 18 cleared · 2013-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243646/> 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 13, 2026