

K161976 Ziehm Solo FDOct 6, 2016
80 days to decisionK161976 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k161976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 18, 2016
Decision date	Oct 6, 2016
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ziehm Imaging GmbH
Location	Orlando, FL, US
Contact	RICHARD L. WESTRICH
510(k) history	18 submissions · 18 cleared · 2013-2025

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