

**K190497 Ziehm 8000**Nov 20, 2019  
265 days to decisionK190497 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k190497/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Feb 28, 2019
Decision date	Nov 20, 2019
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ziehm Imaging GmbH</b>
Location	Orlando, FL, US
Contact	Steve Seeman
510(k) history	18 submissions · 18 cleared · 2013-2025

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