

**K203428 Ziehm Vision RFD**Mar 17, 2021  
117 days to decisionK203428 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k203428/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Nov 20, 2020
Decision date	Mar 17, 2021
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Ziehm-Orthoscan, Inc.</b>
Contact	Steve Seeman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203428/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026