

K240020 Ziehm Vision FDJan 30, 2024
28 days to decisionK240020 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k240020/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Jan 2, 2024 |
| Decision date | Jan 30, 2024 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240020/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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