

K133580 ARTIS ONEApr 28, 2014
158 days to decisionK133580 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k133580/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Nov 21, 2013 |
| Decision date | Apr 28, 2014 |
| Days to decision | 158 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Siemens Medical Solutions USA, Inc. |
| Location | Hoffman Estates, IL, US |
| Contact | PATRICIA D JONES |
| 510(k) history | 778 submissions · 778 cleared · 1980-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133580/> 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 15, 2026