

**K163286 ARTIS pheno**Mar 9, 2017  
107 days to decisionK163286 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k163286/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 22, 2016
Decision date	Mar 9, 2017
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Medical Solution USA, Inc.</b>
Location	Malvern, PA, US
Contact	PATRICIA D. JONES
510(k) history	8 submissions · 8 cleared · 2017-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163286/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026