

**K210054 Cios Spin**Feb 5, 2021  
28 days to decisionK210054 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k210054/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 8, 2021
Decision date	Feb 5, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Medical Systems USA, Inc.</b>
Location	Malvern, PA, US
Contact	Cordell Fields
510(k) history	2 submissions · 2 cleared · 2018-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Siemens Healthcare GmbH</b>
Contact	Cordell Fields

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/k210054/> 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 27, 2026