

**K120282 CARDNAV**Dec 10, 2012  
314 days to decisionK120282 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k120282/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 31, 2012
Decision date	Dec 10, 2012
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Paieon, Inc.</b>
Location	New York, NY, US
Contact	SHIMON VAKNIN
510(k) history	8 submissions · 8 cleared · 2004-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120282/> 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 17, 2026