

**K131854 CEROX**Sep 13, 2013  
84 days to decisionK131854 · Product code: **DPW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k131854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Jun 21, 2013
Decision date	Sep 13, 2013
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Or-Nim Medical , Ltd.</b>
Location	Washington, DC, US
Contact	MICHA OESTEREICH
510(k) history	5 submissions · 5 cleared · 2008-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131854/> 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 June 3, 2026