

**K153605 ivWatch Model 400**Feb 11, 2016  
56 days to decisionK153605 · Product code: **PMS** · General Hospital  
Source: <https://www.510kdatabase.net/k153605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Intravenous (piv) Infiltration Monitor (PMS)
Date received	Dec 17, 2015
Decision date	Feb 11, 2016
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ivwatch, LLC</b>
Location	Williamsburg, VA, US
Contact	Jaclyn Lautz
510(k) history	6 submissions · 6 cleared · 2015-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153605/> 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