

K162478 ivWatchDec 22, 2016
107 days to decisionK162478 · Product code: **PMS** · General Hospital
Source: <https://www.510kdatabase.net/k162478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Intravenous (piv) Infiltration Monitor (PMS)
Date received	Sep 6, 2016
Decision date	Dec 22, 2016
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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