

K233881 ivWatch® Model 400Mar 15, 2024
98 days to decisionK233881 · Product code: **PMS** · General Hospital
Source: <https://www.510kdatabase.net/k233881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Intravenous (piv) Infiltration Monitor (PMS)
Date received	Dec 8, 2023
Decision date	Mar 15, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233881/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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