

K222212 ivWatch Model 400Aug 24, 2022
30 days to decisionK222212 · Product code: **PMS** · General Hospital
Source: <https://www.510kdatabase.net/k222212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Intravenous (piv) Infiltration Monitor (PMS)
Date received	Jul 25, 2022
Decision date	Aug 24, 2022
Days to decision	30 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

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