

**K250460 WatchPAT400 (WP400)**Sep 5, 2025  
199 days to decisionK250460 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k250460/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Feb 18, 2025
Decision date	Sep 5, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Itamar Medical , Ltd.</b>
Location	Washington, DC, US
Contact	Dafna Raiman
510(k) history	11 submissions · 11 cleared · 2011-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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