

K203839 WatchPAT200U (WP200U)Mar 21, 2022
446 days to decisionK203839 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k203839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 30, 2020
Decision date	Mar 21, 2022
Days to decision	446 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Itamar Medical , Ltd.
Location	Washington, DC, US
Contact	Efrat Litman
510(k) history	11 submissions · 11 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan Kahan

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

CLINICAL EVIDENCE - NCT01570738**Validation of Home Sleep Testing (WP) Compared to an Overnight Sleep Testing in the Sleep Laboratory**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	274 patients (actual)
Study sites	1 site
Condition studied	Sleep Disorders
Study type	Observational
Completion date	Jun 1, 2022
Sponsor	Itamar-Medical, Israel (Industry)

Primary outcome

Compare sleep data collected from the Watch-PAT device to PSG data

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01570738