FDA 510(k) Premarket Notification

K223675 WatchPAT ONE (WP1)

CLEARED

Jan 6, 2023
30 days to decision

K223675 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k223675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 7, 2022
Decision date	Jan 6, 2023
Days to decision	30 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