FDA 510(k) Premarket Notification

K222331 WatchPAT300 (WP300)

CLEARED

Sep 14, 2022
43 days to decision

K222331 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k222331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Aug 2, 2022
Decision date	Sep 14, 2022
Days to decision	43 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