

K254042 WatchPAT SW

Jul 31, 2026
227 days to decision

K254042 · Product code: MNR · Anesthesiology
Source: <https://www.510kdatabase.net/k254042/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 16, 2025
Decision date	Jul 31, 2026
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Itamar Medical , Ltd.
Location	Washington, DC, US
Contact	Dafna Raiman
510(k) history	12 submissions · 12 cleared · 2011-2026