

**K180775 Watch-PAT300**Aug 17, 2018  
147 days to decisionK180775 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k180775/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Mar 23, 2018
Decision date	Aug 17, 2018
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180775/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026