

K153070 Watch-PAT200UJul 26, 2016
278 days to decisionK153070 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k153070/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Effort Recorder (MNR) |
| Date received | Oct 22, 2015 |
| Decision date | Jul 26, 2016 |
| Days to decision | 278 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153070/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026