

K251574 Sleep WatchJul 31, 2025
70 days to decisionK251574 · Product code: **LEL** · Neurology
Source: <https://www.510kdatabase.net/k251574/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Device, Sleep Assessment (LEL) |
| Date received | May 22, 2025 |
| Decision date | Jul 31, 2025 |
| Days to decision | 70 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ambulatory Monitoring, Inc. |
| Location | Ardley, NY, US |
| Contact | Paul Chen |
| 510(k) history | 3 submissions · 3 cleared · 1986-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251574/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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