

K181077 ActiGraph CentrePoint Insight WatchMay 24, 2018
30 days to decisionK181077 · Product code: **LEL** · Neurology
Source: <https://www.510kdatabase.net/k181077/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Device, Sleep Assessment (LEL) |
| Date received | Apr 24, 2018 |
| Decision date | May 24, 2018 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Actigraph |
| Location | Pensacola, FL, US |
| Contact | Brian Bell |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181077/> 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 30, 2026