

K120450 SLEEP PROFILERSep 19, 2012
218 days to decisionK120450 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k120450/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ) |
| Date received | Feb 14, 2012 |
| Decision date | Sep 19, 2012 |
| Days to decision | 218 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Advanced Brain Monitoring, Inc. |
| Location | Carlsbad, CA, US |
| Contact | ADRIENNE LENZ |
| 510(k) history | 14 submissions · 14 cleared · 2004-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120450/> 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 24, 2026