

K150688 IdentEventNov 5, 2015
233 days to decisionK150688 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k150688/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automatic Event Detection Software For Full-montage Electroencephalograph (OMB) |
| Date received | Mar 17, 2015 |
| Decision date | Nov 5, 2015 |
| Days to decision | 233 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Optima Neuroscience, Inc. |
| Location | Newberry, FL, US |
| Contact | Ryan T. Kern |
| 510(k) history | 2 submissions · 2 cleared · 2009-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150688/> 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 June 3, 2026