

K092039 IDENTEVENT, VERSION 1.0GOct 16, 2009
102 days to decisionK092039 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k092039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Jul 6, 2009
Decision date	Oct 16, 2009
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optima Neuroscience, Inc.
Location	Newberry, FL, US
Contact	PAULA WILKERSON
510(k) history	2 submissions · 2 cleared · 2009-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092039/> 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