FDA 510(k) Premarket Notification

K092039 IDENTEVENT, VERSION 1.0G

CLEARED

Oct 16, 2009
102 days to decision

K092039 · 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