

K153412 Sleep ProfilerMar 14, 2016
110 days to decisionK153412 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k153412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Nov 25, 2015
Decision date	Mar 14, 2016
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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