

K152040 X8 System - Sleep Profiler (SP40), X8 System - Sleep Profiler PSG2 (SP29), X8 System - Stat X8 (XS29)Oct 30, 2015
100 days to decisionK152040 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k152040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Jul 22, 2015
Decision date	Oct 30, 2015
Days to decision	100 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152040/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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