

**K944833 DIGITRACE SLEEP COMPUTER, SLEPPAC, HOME SLEEP SYSTEM**May 4, 1995  
216 days to decisionK944833 · Product code: **OMB** · Neurology  
Source: <https://www.510kdatabase.net/k944833/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Sep 30, 1994
Decision date	May 4, 1995
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New England Medical Monitoring Co.</b>
Location	Boston, MA, US
Contact	PETER B LEONE
510(k) history	1 submissions · 1 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944833/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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