

**K973596 SPACELABS MEDICAL 90482 BISPECTRAL INDEX  
ANALYSIS (BIS) MODULE**Feb 3, 1998  
134 days to decisionK973596 · Product code: **OLW** · Neurology  
Source: <https://www.510kdatabase.net/k973596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Sep 22, 1997
Decision date	Feb 3, 1998
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spacelabs Medical, Inc.</b>
Location	Hamden, CT, US
Contact	RUSS GARRISON
510(k) history	35 submissions · 34 cleared · 1993-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973596/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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