

**K060900 SPACELABS MEDICAL BISPECTRAL INDEX (BISX)
ANALYSIS MODULE 91482 AND ACCESSORIES MODEL-91842**Jun 23, 2006
81 days to decisionK060900 · Product code: **OLW** · Neurology
Source: <https://www.510kdatabase.net/k060900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Apr 3, 2006
Decision date	Jun 23, 2006
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spacelabs Medical, Inc.
Location	Hamden, CT, US
Contact	AL VAN HOUDT
510(k) history	35 submissions · 34 cleared · 1993-2012

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