

K010728 HARMONE-SCHWARZER EEG SYSTEMMay 21, 2001
70 days to decisionK010728 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k010728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Mar 12, 2001
Decision date	May 21, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Stellate Systems
Location	Westmount, Quebec, CA
Contact	GEORGE PAPAGIANNIS
510(k) history	7 submissions · 7 cleared · 1991-2011

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