

K013450 NOTTA AMBULATORY RECORDERJan 14, 2002
89 days to decisionK013450 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k013450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Oct 17, 2001
Decision date	Jan 14, 2002
Days to decision	89 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026