

K050425 AURA-PSGOct 20, 2005
244 days to decisionK050425 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k050425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Feb 18, 2005
Decision date	Oct 20, 2005
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astro-Med, Inc.
Location	West Warwick, RI, US
Contact	MICHAEL J SULLIVAN
510(k) history	13 submissions · 13 cleared · 1989-2008

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