

K062943 POLYSMITH SLEEP SYSTEM, MODEL NTI5498May 9, 2007
223 days to decisionK062943 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k062943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Sep 28, 2006
Decision date	May 9, 2007
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Neurotronics, Inc.
Location	Gainesville, FL, US
Contact	JENNIFER LAINE
510(k) history	9 submissions · 9 cleared · 1997-2022

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