

K161650 Polysmith Sleep System, Model NTI7593Jan 19, 2017
218 days to decisionK161650 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k161650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Jun 15, 2016
Decision date	Jan 19, 2017
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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