FDA 510(k) Premarket Notification

K131415 LIVE VIEW PANEL (LVP)

CLEARED

Aug 9, 2013
85 days to decision

K131415 · Product code: **OLV** · Neurology
Source: https://www.510kdatabase.net/k131415/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	May 16, 2013
Decision date	Aug 9, 2013
Days to decision	85 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