FDA 510(k) Premarket Notification

K181709 Serenity Piezo Sensor, Serenity Thermocouple Sensor

CLEARED

Nov 16, 2018
141 days to decision

K181709 · Product code: **OLV** · Neurology
Source: https://www.510kdatabase.net/k181709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Jun 28, 2018
Decision date	Nov 16, 2018
Days to decision	141 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