

K173868 Serenity Body Position Sensor, Serenity RIP SensorsJul 2, 2018
194 days to decisionK173868 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k173868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Dec 20, 2017
Decision date	Jul 2, 2018
Days to decision	194 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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