

**K181709 Serenity Piezo Sensor, Serenity Thermocouple Sensor**Nov 16, 2018  
141 days to decisionK181709 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k181709/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181709/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026