

K162627 EnsoSleepMar 31, 2017
192 days to decisionK162627 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k162627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Sep 20, 2016
Decision date	Mar 31, 2017
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ensodata, Inc.
Location	Madison, WI, US
Contact	Chris Fernandez
510(k) history	2 submissions · 2 cleared · 2017-2021

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