

K210034 EnsoSleepJun 16, 2021
161 days to decisionK210034 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k210034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Jan 6, 2021
Decision date	Jun 16, 2021
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210034/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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