

K182227 Esprit NovaJan 17, 2019
154 days to decisionK182227 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k182227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Aug 16, 2018
Decision date	Jan 17, 2019
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurozone Msh Incorporated
Location	Dundas, CA
Contact	Daniel Ramirez Rodriguez
510(k) history	1 submissions · 1 cleared · 2019-2019

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