

K192469 Nox Sleep SystemNov 13, 2019
65 days to decisionK192469 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k192469/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Sep 9, 2019
Decision date	Nov 13, 2019
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nox Medical
Location	Reykjavik, IS
Contact	Kolburn E Ottosdottir
510(k) history	3 submissions · 3 cleared · 2008-2019

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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