

K213007 Cerebra Sleep SystemJul 6, 2022
289 days to decisionK213007 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k213007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Sep 20, 2021
Decision date	Jul 6, 2022
Days to decision	289 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cerebra Medical , Ltd.
Location	Winnipeg, CA
Contact	Sharon Cholowsky
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Mary Vater

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

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