

K192624 ApneaTrakFeb 20, 2020
150 days to decisionK192624 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k192624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Sep 23, 2019
Decision date	Feb 20, 2020
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cadwell Industries, Inc.
Location	Kennewick, WA, US
Contact	James Blevins
510(k) history	12 submissions · 12 cleared · 2014-2025

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