

K231532 ActiGraph LEAP activity monitor (ActiGraph LEAP)Jun 23, 2023
28 days to decisionK231532 · Product code: **LEL** · Neurology
Source: <https://www.510kdatabase.net/k231532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Sleep Assessment (LEL)
Date received	May 26, 2023
Decision date	Jun 23, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Actigraph, LLC
Location	Pensacola, FL, US
Contact	Brian Bell
510(k) history	2 submissions · 2 cleared · 2008-2023

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