FDA 510(k) Premarket Notification

K233618 Oxevision Sleep Device

CLEARED

Apr 3, 2024
142 days to decision

K233618 · Product code: **LEL** · Neurology
Source: https://www.510kdatabase.net/k233618/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sleep Assessment (LEL)
Date received	Nov 13, 2023
Decision date	Apr 3, 2024
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oxehealth Limited**
Location	Abingdon, GB
Contact	Joao Jorge
510(k) history	6 submissions · 5 cleared · 2021-2026