FDA 510(k) Premarket Notification

K220028 NightOwl

CLEARED

Feb 24, 2022
50 days to decision

K220028 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k220028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 5, 2022
Decision date	Feb 24, 2022
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ectosense NV**
Location	Rotselaar, BE
Contact	Bart Van Pee
510(k) history	3 submissions · 3 cleared · 2020-2022

CLINICAL EVIDENCE - NCT04191668

A Validation Study of the NightOwl PAT-based Home Sleep Apnea Test

Status	Completed
Enrollment	106 patients (actual)
Study sites	3 sites
Condition studied	Sleep Apnea
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 1, 2020
Sponsor	Ectosense NV (Industry)

Primary outcome

Pearson Correlation Between the AHI

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04191668