FDA 510(k) Premarket Notification

K173974 DROWZLE

CLEARED

Jul 14, 2019
562 days to decision

K173974 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k173974/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 29, 2017
Decision date	Jul 14, 2019
Days to decision	562 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Resonea, Inc.**
Location	Scottsdale, AZ, US
Contact	Ruchir Sehra
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Graematter, Inc.**
Contact	Melissa Walker

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

CLINICAL EVIDENCE - NCT03288376

SNORE (Smartphone Analyses of Nocturnal Obstruction by Respiratory Evaluation) SOUNDS

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	272 patients (actual)
Study sites	3 sites
Condition studied	Sleep Apnea, Obstructive; Chronic Obstructive Pulmonary Disease
Study type	Observational
Completion date	Jan 31, 2017
Sponsor	Incyphae, Inc. (Industry)

Primary outcome

Agreement between algorithm with PSG reference standard for detection of OSA at an AHI cut-off of 15

Secondary outcome

Comparison between algorithm and PSG assignment of OSA severity based on AHI [0-4 normal/minimal OSA, 5-14 mild, 15-30 moderate, >30 severe].

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03288376