FDA 510(k) Premarket Notification

K210480 AcuPebble SA

CLEARED

Jul 6, 2021
137 days to decision

K210480 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k210480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Feb 19, 2021
Decision date	Jul 6, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acurable Limited**
Location	London, GB
Contact	Esther Rodriguez-Villegas
510(k) history	3 submissions · 3 cleared · 2021-2025

CLINICAL EVIDENCE - NCT03544086

Clinical Evaluation of a Wearable Sleep Diagnosis Technology

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	150 patients (actual)
Study sites	1 site
Condition studied	Obstructive Sleep Apnea
Study type	Observational
Completion date	Sep 15, 2020
Sponsor	Acurable Ltd. (Industry)

Primary outcome

Sensitivities and Specificities for diagnosis of sleep apnoea studies

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03544086