

K243092 AcuPebble Ox (200)Mar 19, 2025
170 days to decisionK243092 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k243092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Sep 30, 2024
Decision date	Mar 19, 2025
Days to decision	170 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 - NCT06460246

Pulse Oximeter Accuracy During Stable Hypoxia Plateaus

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	12 patients (actual)
Study sites	1 site
Condition studied	Healthy
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 31, 2024
Sponsor	Acurable Ltd. (Industry)

Primary outcome

Performance of the pulse oximeters against corresponding arterial blood oxygen saturation.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06460246
