

K240285 Huxley SANSA Home Sleep Apnea Test (1000-00)Jul 15, 2024
165 days to decisionK240285 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k240285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Feb 1, 2024
Decision date	Jul 15, 2024
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huxley Medical
Location	Atlanta, GA, US
Contact	Brennan Torstrick
510(k) history	4 submissions · 4 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Powers Regulatory Consulting
Contact	Grace Powers

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT06070389****Polysomnography Validation of the Sansa Device**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	533 patients (actual)
Study sites	2 sites
Condition studied	Sleep-Disordered Breathing
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 13, 2023
Sponsor	Huxley Medical, Inc. (Industry)

Primary outcome

Sensitivity and Specificity of the Sansa device to detect sleep disordered breathing compared to polysomnography

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06070389