FDA 510(k) Premarket Notification

K250882 SANSA HSAT

CLEARED

Oct 29, 2025
219 days to decision

K250882 · Product code: **MNR** · Cardiovascular
Source: https://www.510kdatabase.net/k250882/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Mar 24, 2025
Decision date	Oct 29, 2025
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Huxley Medical**
Location	Atlanta, GA, US
Contact	Daniel Burnham
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

CLINICAL EVIDENCE - NCT06414447

Electrocardiogram (ECG) Validation Study

Status	Not yet recruiting - *No results published to ClinicalTrials.gov*
Enrollment	15 patients (estimated)
Condition studied	Arrythmia
Study type	Observational
Completion date	Jul 1, 2024
Sponsor	Huxley Medical, Inc. (Industry)

Primary outcome

Comparison of the diagnostic Electrocardiogram (ECG) signal quality of the P, QRS and T wave deflections of the Sansa device to a reference standard Holter monitor

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06414447