

K252497 SANSA HSATDec 10, 2025
124 days to decisionK252497 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k252497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Aug 8, 2025
Decision date	Dec 10, 2025
Days to decision	124 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

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