

K244027 SANSA HSATJan 28, 2025
29 days to decisionK244027 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k244027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 30, 2024
Decision date	Jan 28, 2025
Days to decision	29 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](https://accessdata.fda.gov)

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