

K240100 SAM Model 9-10000Jun 4, 2024
144 days to decisionK240100 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k240100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 12, 2024
Decision date	Jun 4, 2024
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Snap Diagnostics, LLC
Location	Wheeling, IL, US
Contact	Gil Raviv
510(k) history	2 submissions · 2 cleared · 2011-2024

REGULATORY CONSULTANT

Consulting firm	Vision28
Contact	Tom Renner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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