FDA 510(k) Premarket Notification

K240100 SAM Model 9-10000

CLEARED

Jun 4, 2024
144 days to decision

K240100 · 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