FDA 510(k) Premarket Notification

K233452 Vivo 45 LS

CLEARED

Jan 13, 2025
451 days to decision

K233452 · Product code: **NOU** · Anesthesiology
Source: https://www.510kdatabase.net/k233452/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous, Ventilator, Home Use (NOU)
Date received	Oct 20, 2023
Decision date	Jan 13, 2025
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Breas Medical AB**
Location	Molnlycke, Vastra Gotaland, SE
Contact	Ivan Liljegren
510(k) history	15 submissions · 15 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	**O'Connell Regulatory Consultants, Inc.**
Contact	Maureen O'Connell

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