FDA 510(k) Premarket Notification

K240778 Vivo 1, Vivo 2

CLEARED

Dec 13, 2024
267 days to decision

K240778 · Product code: **MNS** · Anesthesiology
Source: https://www.510kdatabase.net/k240778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Mar 21, 2024
Decision date	Dec 13, 2024
Days to decision	267 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	**Oconnell Regulatory Consultants, Inc.**
Contact	Maureen OConnell

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