

K232365 Vivo 45 LSDec 19, 2025
865 days to decisionK232365 · Product code: **CBK** · AnesthesiologySource: <https://www.510kdatabase.net/k232365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Aug 7, 2023
Decision date	Dec 19, 2025
Days to decision	865 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oconnell Regulatory Consultants, Inc.
Location	Stoneham, MA, US
Contact	Maureen OConnell
510(k) history	1 submissions · 1 cleared · 2025-2025

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