

**K240779 Vivo 3**Dec 13, 2024  
267 days to decisionK240779 · Product code: **MNT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k240779/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Oconnell Regulatory Consultants, Inc.</b>
Contact	Maureen OConnell

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240779/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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