

**K193586 Vivo 45 LS**Jan 27, 2021  
401 days to decisionK193586 · Product code: **NOU** · Anesthesiology  
Source: <https://www.510kdatabase.net/k193586/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous, Ventilator, Home Use (NOU)
Date received	Dec 23, 2019
Decision date	Jan 27, 2021
Days to decision	401 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	Ari Sobel
510(k) history	15 submissions · 15 cleared · 2006-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>O&amp;apos;Connell Regulatory Consultants, Inc.</b>
Contact	Maureen O&apos;Connell

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/k193586/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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