

K160481 Vivo 60Nov 9, 2016
261 days to decisionK160481 · Product code: **NOU** · Anesthesiology
Source: <https://www.510kdatabase.net/k160481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous, Ventilator, Home Use (NOU)
Date received	Feb 22, 2016
Decision date	Nov 9, 2016
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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