

K063476 BREAS ISLEEP 20IJan 22, 2007
67 days to decisionK063476 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k063476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 16, 2006
Decision date	Jan 22, 2007
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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