

K061057 BREAS ISLEEP 20+Jun 23, 2006
67 days to decisionK061057 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k061057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Apr 17, 2006
Decision date	Jun 23, 2006
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061057/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026