

**K060657 ISLEEP BY BREAS, MODELS ISLEEP 10, ISLEEP 20.**Aug 18, 2006  
158 days to decisionK060657 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k060657/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 13, 2006
Decision date	Aug 18, 2006
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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