

**K061099 BREATHX NASAL PILLOW AND MASK SYSTEM,  
MODEL 011-0003**Aug 11, 2006  
114 days to decisionK061099 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k061099/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Apr 19, 2006
Decision date	Aug 11, 2006
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hoffman Laboratories, LLC</b>
Location	Chatsworth, CA, US
Contact	KEITH BOSECKER
510(k) history	2 submissions · 2 cleared · 2005-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061099/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026