

K052597 BREATHEX OMEGA CPAP DEVICE, MODEL 322Dec 16, 2005
86 days to decisionK052597 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k052597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 21, 2005
Decision date	Dec 16, 2005
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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