

K082866 REVOLUTIONFULL FACE MASKJan 30, 2009
123 days to decisionK082866 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k082866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 29, 2008
Decision date	Jan 30, 2009
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Respironics Inc., Sleep & Home Respiratory Group
Location	Murrysville, PA, US
Contact	ANDREW ZELTWANGER
510(k) history	21 submissions · 21 cleared · 2007-2010

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