

K092835 COMFORTGEL NASAL MASKFeb 12, 2010
150 days to decisionK092835 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k092835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 15, 2009
Decision date	Feb 12, 2010
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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