

K063830 REMSTAR AFLEX CPAP SYSTEMMar 9, 2007
73 days to decisionK063830 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k063830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 26, 2006
Decision date	Mar 9, 2007
Days to decision	73 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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