

K092648 RESPIRONICS PERFORMAX SE TOTAL FACE MASKDec 18, 2009
112 days to decisionK092648 · Product code: **CBK** · Anesthesiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Aug 28, 2009
Decision date	Dec 18, 2009
Days to decision	112 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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