

K102454 I-NEB AAD SYSTEM WITH TIMOct 25, 2011
424 days to decisionK102454 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k102454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 27, 2010
Decision date	Oct 25, 2011
Days to decision	424 days
Third-party review	No
Summary / Statement	Summary
Other names	I-NEB INSIGHT AAD SYSTEM

APPLICANT

Company	Respironics Respiratory Drug Delivery (UK) , Ltd.
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	2 submissions · 2 cleared · 2011-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102454/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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