

K042991 I-NEB AAD SYSTEMSep 23, 2005
326 days to decisionK042991 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k042991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 1, 2004
Decision date	Sep 23, 2005
Days to decision	326 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Profile Therapeutics Plc
Location	Mccordsville, IN, US
Contact	BARBARA CAMPBELL
510(k) history	3 submissions · 3 cleared · 2004-2005

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