

K102240 NIVO NEBULIZER SYSTEMNov 10, 2010
93 days to decisionK102240 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k102240/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 9, 2010
Decision date	Nov 10, 2010
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Aerogen (Ireland), Ltd.
Location	Dangan Galway, IE
Contact	CAITRIONA CONNEELY
510(k) history	3 submissions · 3 cleared · 2007-2010

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