

K123614 SOLARYS VENTILATOR AEROSOL DELIVERY SYSTEM (AS)Mar 11, 2013
108 days to decisionK123614 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k123614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 23, 2012
Decision date	Mar 11, 2013
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trudell Medical Intl.
Location	London, CA
Contact	DARRYL FISCHER
510(k) history	12 submissions · 12 cleared · 2002-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123614/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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