

**K123400 AEROBIKA POSITIVE EXPIRATORY PRESSURE
DEVICE**May 16, 2013
192 days to decisionK123400 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k123400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Nov 5, 2012
Decision date	May 16, 2013
Days to decision	192 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/k123400/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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