

K042945 AURA CPAP SYSTEMMar 9, 2005
135 days to decisionK042945 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k042945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Oct 25, 2004
Decision date	Mar 9, 2005
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aeionmed, Inc.
Location	Stoughton, WI, US
Contact	Gary Syring
510(k) history	4 submissions · 4 cleared · 2004-2010

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