

K100528 BREATHE TECHNOLOGIES VENTILATOR AND ACCESSORIES BT-V2SApr 23, 2010
58 days to decisionK100528 · Product code: **ONZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k100528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Ventilator (ONZ)
Date received	Feb 24, 2010
Decision date	Apr 23, 2010
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Breathe Technologies, Inc.
Location	Alameda, CA, US
Contact	SUZON LOMMEL
510(k) history	5 submissions · 5 cleared · 2009-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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