

K131562 BREATHE NIOV VENTILATION SYSTEMMar 6, 2014
280 days to decisionK131562 · Product code: **ONZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k131562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Ventilator (ONZ)
Date received	May 30, 2013
Decision date	Mar 6, 2014
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Breathe Technologies
Location	Alameda, CA, US
Contact	CRAIG COOMBS
510(k) history	3 submissions · 3 cleared · 2014-2017

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