

K152664 TAV SystemDec 2, 2016
442 days to decisionK152664 · Product code: **ONZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k152664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Ventilator (ONZ)
Date received	Sep 17, 2015
Decision date	Dec 2, 2016
Days to decision	442 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Aera, Inc.
Location	San Ramon, CA, US
Contact	ERIC JOHANSSON
510(k) history	1 submissions · 1 cleared · 2016-2016

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