

**K172875 Astral 100/150**Apr 26, 2018  
217 days to decisionK172875 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k172875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Sep 21, 2017
Decision date	Apr 26, 2018
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Resmed, Ltd.</b>
Location	Poway, CA, US
Contact	Peter Jennings
Website	<a href="http://www.resmed.com/">http://www.resmed.com/</a>
510(k) history	103 submissions · 103 cleared · 1996-2019

**REGULATORY CONSULTANT**

Consulting firm	<b>Resmed Corp (Registration Number: 3007573469)</b>
Contact	Sheila Bruschi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT02683772****Astral VAPS AutoEPAP Clinical Trial**

Status	Completed
Enrollment	42 patients (actual)
Study sites	5 sites
Condition studied	Upper Airway Obstruction; Respiratory Insufficiency; Respiratory Failure
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Single blind
Completion date	Jul 6, 2017
Sponsor	ResMed (Industry)

**Primary outcome**

Oxygen Desaturation Index 4% (ODI4%)

**Secondary outcome**

Sleep Efficiency (%)

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02683772](https://clinicaltrials.gov/study/NCT02683772)