

**K180497 Scone Mask**Jun 15, 2018  
109 days to decisionK180497 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k180497/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 26, 2018
Decision date	Jun 15, 2018
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180497/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026