

**K112546 O\_TWO CPAP SYSTEM**Dec 27, 2011  
117 days to decisionK112546 · Product code: **BYE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k112546/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Sep 1, 2011
Decision date	Dec 27, 2011
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>O-Two Medical Technologies, Inc.</b>
Location	Mississauga, CA
Contact	AMMAR AL-DOJAILY
510(k) history	8 submissions · 8 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112546/> 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 May 24, 2026