

**K071915 CPAP MASK**May 14, 2008  
308 days to decisionK071915 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k071915/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jul 11, 2007
Decision date	May 14, 2008
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Arcimed Laboratories, LLC</b>
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	1 submissions · 1 cleared · 2008-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071915/> 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