

**K052804 BREATHKEY MODEL G10/BREATHKEY MODEL G30X**Dec 9, 2005  
66 days to decisionK052804 · Product code: **DJZ** · Chemistry  
Source: <https://www.510kdatabase.net/k052804/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices, Breath Trapping, Alcohol (DJZ)
Date received	Oct 4, 2005
Decision date	Dec 9, 2005
Days to decision	66 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omega Point Systems, LLC</b>
Location	Cincinnati, OH, US
Contact	BARBARA S FANT
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052804/> 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 29, 2026