

**K130524 BREATHID HP SYSTEM**May 22, 2013  
83 days to decisionK130524 · Product code: **MSQ** · Microbiology  
Source: <https://www.510kdatabase.net/k130524/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	Feb 28, 2013
Decision date	May 22, 2013
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exalenz Bioscience , Ltd.</b>
Location	Wheat Ridge, CO, US
Contact	CLAY ANSELMO
510(k) history	5 submissions · 5 cleared · 2013-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130524/> 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 20, 2026