

**K011668 VALIDATION OF THE BREATHID SYSTEM, FOR THE  
DETECTION OF HELICBACTOR PYLORI**Jul 9, 2001  
53 days to decisionK011668 · Product code: **MSQ** · Microbiology  
Source: <https://www.510kdatabase.net/k011668/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Urea (breath Or Blood) (MSQ)
Date received	May 17, 2001
Decision date	Jul 9, 2001
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oridion Medical 1987 , Ltd.</b>
Location	Jerusalem, IL
Contact	SANDY BROWN
510(k) history	19 submissions · 19 cleared · 2001-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011668/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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