

**K923445 PYLORAGEN HELICBACTER PYLORI TEST KIT -  
MODIFIED**Sep 11, 1992  
65 days to decisionK923445 · Product code: LYR · Microbiology  
Source: <https://www.510kdatabase.net/k923445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Jul 8, 1992
Decision date	Sep 11, 1992
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hycor Biomedical, Inc.</b>
Location	Garden Grove, CA, US
Contact	RONALD HOOVER
510(k) history	51 submissions · 51 cleared · 1989-2008

Hycor Biomedical, Inc. is an American manufacturer of in vitro diagnostic products for blood testing. The company is based in Garden Grove, California and specializes in allergy and autoimmune testing solutions. Hycor Biomedical has received FDA 510(k) clearances from total submissions since its first clearance in 1989. The company's regulatory portfolio is dominated by Immunology devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance on record dates to 2008, reflecting the company's historical significance in the diagnostic devi...

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Device record: <https://www.510kdatabase.net/k923445/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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