

**K991697 UNI-GOLD H. PYLORI**Dec 21, 1999  
217 days to decisionK991697 · Product code: **LYR** · Microbiology  
Source: <https://www.510kdatabase.net/k991697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	May 18, 1999
Decision date	Dec 21, 1999
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trinity Biotech, Plc</b>
Location	Jamestown, NY, US
Contact	Erika B Ammirati
510(k) history	5 submissions · 5 cleared · 1999-2002

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