

**K904655 PYLORISSET**Oct 21, 1991  
374 days to decisionK904655 · Product code: LYR · Microbiology  
Source: <https://www.510kdatabase.net/k904655/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Oct 12, 1990
Decision date	Oct 21, 1991
Days to decision	374 days
Third-party review	No

**APPLICANT**

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Company	<b>Orion Diagnostica, Inc.</b>
Location	Mchenry, IL, US
Contact	TIMO RAINES
510(k) history	28 submissions · 28 cleared · 1980-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k904655/>; 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 30, 2026