

K052708 PYLO-PLUSMay 1, 2006
214 days to decisionK052708 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k052708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Sep 29, 2005
Decision date	May 1, 2006
Days to decision	214 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Arj Medical, Inc.
Location	Oldsmar, FL, US
Contact	PHILIP ROSS
510(k) history	3 submissions · 3 cleared · 2006-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052708/> Data sourced from FDA 510(k) public records (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. - Generated June 21, 2026