

K883641 SELECTIVE RAPID UREAMay 4, 1989
252 days to decisionK883641 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k883641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Aug 25, 1988
Decision date	May 4, 1989
Days to decision	252 days
Third-party review	No

APPLICANT

Company	Remel Co.
Location	Mchenry, IL, US
Contact	BRENDA HENRY
510(k) history	137 submissions · 137 cleared · 1979-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883641/>, 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 May 14, 2026