

K984544 THE APTUS (AUTOMATED) APPLICATION OF THE HM-CAP EIA KIT. AN ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF THE SFeb 18, 1999
58 days to decisionK984544 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k984544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Dec 22, 1998
Decision date	Feb 18, 1999
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Enteric Products, Inc.
Location	Stony Brook, NY, US
Contact	JEFFREY PEACOCK
510(k) history	2 submissions · 2 cleared · 1999-2000

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