

K052716 RAPIRUN H. PYLORI ANTIBODY DETECTION KITNov 16, 2006
413 days to decisionK052716 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k052716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Sep 29, 2005
Decision date	Nov 16, 2006
Days to decision	413 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Otsuka Pharmaceutical Co., Ltd.
Location	Rockville, MD, US
Contact	CYNTHIA A SINCLAIR
Website	http://www.otsuka.co.jp
510(k) history	6 submissions · 6 cleared · 1999-2010

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