

K003794 ELISA TEST, SEROLOGYMar 30, 2001
112 days to decisionK003794 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k003794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Dec 8, 2000
Decision date	Mar 30, 2001
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Micro Detect, Inc.
Location	Tustin, CA, US
Contact	MEDHI ALEM
510(k) history	11 submissions · 11 cleared · 1998-2001

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