

K955085 HM-CAP EIA TEST (MODIFICATION)Feb 9, 1996
106 days to decisionK955085 · Product code: LYR · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Oct 26, 1995
Decision date	Feb 9, 1996
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Schiff & Co.
Location	West Cadwell, NJ, US
Contact	Gary Lehnus
510(k) history	15 submissions · 15 cleared · 1988-1999

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