

**K871105 THE GONOGEN II TEST KIT FOR NEISSERIA
GONORRHOEAE**May 13, 1987
55 days to decisionK871105 · Product code: **LIC** · Microbiology
Source: <https://www.510kdatabase.net/k871105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Coagglutination (direct) Neisseria Gonorrhoeae (LIC)
Date received	Mar 19, 1987
Decision date	May 13, 1987
Days to decision	55 days
Third-party review	No

APPLICANT

Company	New Horizons Diagnostics Co.
Location	Mchenry, IL, US
Contact	DAVID TRUDIL
510(k) history	10 submissions · 10 cleared · 1982-1995

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