

K881064 HYGEIA GC TESTJun 2, 1988
80 days to decisionK881064 · Product code: **LIR** · Microbiology
Source: <https://www.510kdatabase.net/k881064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Enzyme Linked Immunoabsorbent Assay, Neisseria Gonorrhoeae (LIR)
Date received	Mar 14, 1988
Decision date	Jun 2, 1988
Days to decision	80 days
Third-party review	No

APPLICANT

Company	Hygeia Sciences
Location	Newton, MA, US
Contact	CANNON, PHD
510(k) history	4 submissions · 4 cleared · 1986-1988

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