

K023947 GC OIAApr 17, 2003
141 days to decisionK023947 · Product code: **LIR** · Microbiology
Source: <https://www.510kdatabase.net/k023947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Enzyme Linked Immunoabsorbent Assay, Neisseria Gonorrhoeae (LIR)
Date received	Nov 27, 2002
Decision date	Apr 17, 2003
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermo Biostar, Inc.
Location	Boulder, CO, US
Contact	JOHN G ADAMS
510(k) history	5 submissions · 5 cleared · 2002-2004

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