

**K921075 PHADEBACT MONOCLONAL GC TEST,
MODIFICATION**May 22, 1992
84 days to decisionK921075 · Product code: **LIC** · Microbiology
Source: <https://www.510kdatabase.net/k921075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Coagglutination (direct) Neisseria Gonorrhoeae (LIC)
Date received	Feb 28, 1992
Decision date	May 22, 1992
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Karo Bio Diagnostics AB
Location	S-141 44 Huddinge, Sweden, SC
Contact	BENGT GUSTAVSSON
510(k) history	1 submissions · 1 cleared · 1992-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k921075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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