

K984631 BDPROBETEC ET CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE AMPLIFIED DNA ASSAY

Nov 4, 1999
309 days to decision

K984631 · Product code: LSL · Microbiology
Source: <https://www.510kdatabase.net/k984631/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Dec 30, 1998
Decision date	Nov 4, 1999
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton Dickinson Microbiology Systems
Location	Cockeysville, MD, US
Contact	COLLEEN ROHRBECK
510(k) history	33 submissions · 33 cleared · 1992-1999

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Device record: <https://www.510kdatabase.net/k984631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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