

K042390 ETEST FOR GEMIFLOXACINNov 19, 2004
78 days to decisionK042390 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k042390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 2, 2004
Decision date	Nov 19, 2004
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ab Biodisk
Location	Solna, SE
Contact	ANNE BOLMSTROM
510(k) history	64 submissions · 64 cleared · 1991-2008

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