

**K052366 ETEST TIGECYCLINE GRAM POSITIVE AND GRAM
NEGATIVE AEROBIC BACTERIA, STREPTOCOCCUS SPP. AND
ANAEROBIC BACTERIA**Oct 13, 2005
45 days to decisionK052366 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k052366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Aug 29, 2005
Decision date	Oct 13, 2005
Days to decision	45 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026