

**K980347 ETEST TETRACYCLINE**May 27, 1998  
119 days to decisionK980347 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k980347/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jan 28, 1998
Decision date	May 27, 1998
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980347/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 25, 2026