

**K983486 SYSTEM U3 FOR NORFLOXACIN**Dec 23, 1998  
79 days to decisionK983486 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k983486/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Oct 5, 1998
Decision date	Dec 23, 1998
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983486/> 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