

**K983571 SYSTEM U3 FOR TETRACYCLINE**Dec 30, 1998  
78 days to decisionK983571 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k983571/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received         | Oct 13, 1998   |
| Decision date         | Dec 30, 1998   |
| Days to decision      | 78 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/k983571/> 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