

**K081325 ETEST DORIPENEM - ANTIMICROBIAL  
SUSCEPTIBILITY TEST - MIC AT 0.002-32 UG/ML**Jul 24, 2008  
73 days to decisionK081325 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k081325/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received         | May 12, 2008   |
| Decision date         | Jul 24, 2008   |
| Days to decision      | 73 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ab Biodisk</b>                       |
| Location       | Solna, SE                               |
| Contact        | ANETTE ENGELHARDT                       |
| 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/k081325/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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