

**K043589 MICROSCAN DRIED GRAM-POSITIVE MIC/COMBO  
PANELS - ERTAPENEM**Feb 14, 2005  
48 days to decisionK043589 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k043589/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received         | Dec 28, 2004   |
| Decision date         | Feb 14, 2005   |
| Days to decision      | 48 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dade Microscan, Inc.</b>             |
| Location       | West Sacramento, CA, US                 |
| Contact        | CYNTHIA VAN DUKER                       |
| 510(k) history | 40 submissions · 40 cleared · 1996-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043589/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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