

K050076 VITEK 2 GRAM POSITIVE ERTAPENEMFeb 18, 2005
37 days to decisionK050076 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k050076/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON) |
| Date received | Jan 12, 2005 |
| Decision date | Feb 18, 2005 |
| Days to decision | 37 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | bioMerieux, Inc. |
| Location | Mchenry, IL, US |
| Contact | JOLYN TENLLADO |
| 510(k) history | 251 submissions · 250 cleared · 1983-2026 |

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