

**K091264 MICROSCAN DRIED GRAM-POSITIVE MIC/COMBO
PANELS, MODEL B1017**

Jul 22, 2009
83 days to decision

K091264 · Product code: LTT · Microbiology
Source: <https://www.510kdatabase.net/k091264/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Panels, Test, Susceptibility, Antimicrobial (LTT) |
| Date received | Apr 30, 2009 |
| Decision date | Jul 22, 2009 |
| Days to decision | 83 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Siemens Healthcare Diagnostics |
| Location | Newark, DE, US |
| Contact | SHANNON POPSON |
| 510(k) history | 92 submissions · 92 cleared · 2008-2025 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k091264/> Data sourced from FDA 510(k) public records (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. - Generated May 28, 2026