

K935704 DRIED GRAM-NEGATIVE MIC//COMBO PANELSApr 14, 1995
500 days to decisionK935704 · Product code: **LTT** · Microbiology
Source: <https://www.510kdatabase.net/k935704/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Panels, Test, Susceptibility, Antimicrobial (LTT) |
| Date received | Nov 30, 1993 |
| Decision date | Apr 14, 1995 |
| Days to decision | 500 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Diagnostics, Inc. |
| Location | Miami, FL, US |
| Contact | ELAINE K CATAPANE |
| Website | https://www.baxter.com/ |
| 510(k) history | 72 submissions · 72 cleared · 1988-1995 |

Baxter Diagnostics, Inc. is a diagnostic device manufacturer based in Miami, US. The company specialized in microbiology and chemistry diagnostic solutions. Baxter Diagnostics received FDA 510(k) clearances from total submissions between 1988 and 1995. The company's regulatory focus centered on microbiology devices, particularly dried antimicrobial susceptibility testing panels and related diagnostic assays. This historical record reflects the company's core expertise in microbial identification and resistance testing. The company is no longer active in FDA 510(k) submiss...
