

K940917 LORACARBEF GRAM-NAGATIVE PANELSFeb 8, 1995
348 days to decisionK940917 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k940917/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received | Feb 25, 1994 |
| Decision date | Feb 8, 1995 |
| Days to decision | 348 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 The company is no longer active in FDA 510(k) submiss...
