

K912680 ANTIGENZ CHLAMYDIAJul 22, 1991
49 days to decisionK912680 · Product code: **LJC** · Microbiology
Source: <https://www.510kdatabase.net/k912680/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, (chlamydiae Group) (LJC) |
| Date received | Jun 3, 1991 |
| Decision date | Jul 22, 1991 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Diagnostics, Inc. |
| Location | Miami, FL, US |
| Contact | NANCY MALLINAK |
| 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 The company is no longer active in FDA 510(k) submiss...
