FDA 510(k) Premarket Notification

**CLEARED**

# K884191 INFLUENZA A IFA TEST FOR DIRECT ANTIGEN DETECTION

Nov 22, 1988
47 days to decision

K884191 · Product code: **GNX** · Microbiology
Source: https://www.510kdatabase.net/k884191/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, Cf (including Cf Control), Influenza Virus A, B, C (GNX) |
| Date received | Oct 6, 1988 |
| Decision date | Nov 22, 1988 |
| Days to decision | 47 days |
| Third-party review | No |

## APPLICANT

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 The company is no longer active in FDA 510(k) submiss...