

K884192 RSV IFA TEST KIT FOR DIRECT ANTIGEN DETECTIONNov 22, 1988
47 days to decisionK884192 · Product code: **LKT** · Microbiology
Source: <https://www.510kdatabase.net/k884192/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus, Antigen, Antibody, Ifa (LKT)
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 The company is no longer active in FDA 510(k) submiss...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k884192/> 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 June 29, 2026