FDA 510(k) Premarket Notification

CLEARED

K884194 PARAINFLUENZA TYPE 1 IFA TEST KIT FOR ANTI. DETECT

Nov 22, 1988
47 days to decision

K884194 · Product code: **GQS** · Microbiology
Source: https://www.510kdatabase.net/k884194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Cf (including Cf Control), Parainfluenza Virus 1-4 (GQS)
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 The company is no longer active in FDA 510(k) submiss...