FDA 510(k) Premarket Notification

CLEARED

K912838 BARTELS RESPIRATORY SYNCYTIAL VIRUS ENZYME IMMUNO

Sep 27, 1991
93 days to decision

K912838 · Product code: **LKT** · Microbiology
Source: https://www.510kdatabase.net/k912838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus, Antigen, Antibody, Ifa (LKT)
Date received	Jun 26, 1991
Decision date	Sep 27, 1991
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...