

**K914202 BARTELS PRIMA SYSTEM ADVANCED SCREENING
CARTRIDGE**Oct 11, 1991
22 days to decisionK914202 · Product code: **JJQ** · Chemistry
Source: <https://www.510kdatabase.net/k914202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Sep 19, 1991
Decision date	Oct 11, 1991
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...

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Device record: <https://www.510kdatabase.net/k914202/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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