

K944604 CX AMPHETAMINES REAGENT FOR SYNCHRON CX SYSTEMSDec 7, 1994
79 days to decisionK944604 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k944604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Sep 19, 1994
Decision date	Dec 7, 1994
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman-Diagnostic Systems Group
Location	Brea, CA, US
Contact	SHERI HALL
510(k) history	11 submissions · 11 cleared · 1993-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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