

K993954 SYNCHRON SYSTEMS DAT MULTI-DRUG LOW AND HIGH URINE CALIBRATORSJan 11, 2000
50 days to decisionK993954 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k993954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Nov 22, 1999
Decision date	Jan 11, 2000
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	LUCINDA STOCKERT
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...