

**K954608 CEDIA DAU MULTI-DR CALIBRATOR/PRI, SEC, INTER,  
HIGH**Dec 26, 1995  
83 days to decisionK954608 · Product code: **DKB** · Chemistry  
Source: <https://www.510kdatabase.net/k954608/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Oct 4, 1995
Decision date	Dec 26, 1995
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
Contact	BETSY SOARES-MADDOX
510(k) history	340 submissions · 340 cleared · 1976-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954608/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026