

K963191 CEDIA ANTIBIOTIC TDM MULTI-CALSSep 10, 1996
26 days to decisionK963191 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k963191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Aug 15, 1996
Decision date	Sep 10, 1996
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963191/> 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