

K855225 ACCU-CHEK II LOW AND HIGH GLUCOSE CONTROLJan 17, 1986
18 days to decisionK855225 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k855225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 30, 1985
Decision date	Jan 17, 1986
Days to decision	18 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k855225/> 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