

K854967 CRITIC - SF, ASSAYEDJan 7, 1986
27 days to decisionK854967 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k854967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Dec 11, 1985
Decision date	Jan 7, 1986
Days to decision	27 days
Third-party review	No

APPLICANT

Company	Dimension Diagnostics
Location	St. Charles, MO, US
Contact	CLYDE E HAM
510(k) history	8 submissions · 8 cleared · 1985-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854967/>; 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 June 30, 2026