

K881229 AUTO TROL(TM) CONTROL, LEVELS 1 & 2 #16692 & 16693May 27, 1988
66 days to decisionK881229 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k881229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Mar 22, 1988
Decision date	May 27, 1988
Days to decision	66 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k881229/> 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 14, 2026