

K934641 I-STAT CONTROL LEVELS 1,2,3Dec 9, 1993
79 days to decisionK934641 · Product code: **JJR** · Chemistry
Source: <https://www.510kdatabase.net/k934641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrolyte Controls (assayed And Unassayed) (JJR)
Date received	Sep 21, 1993
Decision date	Dec 9, 1993
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	I-Stat Corp.
Location	Princeton, NJ, US
Contact	ROBERT F MARTIN
510(k) history	14 submissions · 14 cleared · 1989-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934641/> 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 28, 2026