

K982071 I-STAT LACTATE TESTJun 29, 1998
17 days to decisionK982071 · Product code: **KHP** · Chemistry
Source: <https://www.510kdatabase.net/k982071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Lactic, Enzymatic Method (KHP)
Date received	Jun 12, 1998
Decision date	Jun 29, 1998
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982071/> 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