

K031739 I-STAT CARDIAC TROPONIN (CTNI) TESTSep 2, 2003
90 days to decisionK031739 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k031739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jun 4, 2003
Decision date	Sep 2, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	I-Stat Corporation
Location	East Windsor, NJ, US
Contact	GREGORY W SHIPP
510(k) history	7 submissions · 7 cleared · 2002-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031739/> 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