

K982845 CARDIAC MARKERS CONTROL (SINGLE USE)-LEVELS, 1,2,3, MODELS NUMBER 175-1, 175-2, 175-3Aug 21, 1998
9 days to decisionK982845 · Product code: JJT · Chemistry
Source: <https://www.510kdatabase.net/k982845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Aug 12, 1998
Decision date	Aug 21, 1998
Days to decision	9 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	More Diagnostics
Location	Los Osos, CA, US
Contact	JAMES W SNIPES
510(k) history	16 submissions · 16 cleared · 1993-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982845/> 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 25, 2026