

K883711 QM300 CALIBRATOR F PACKSep 22, 1988
23 days to decisionK883711 · Product code: **DFC** · Immunology
Source: <https://www.510kdatabase.net/k883711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Aug 30, 1988
Decision date	Sep 22, 1988
Days to decision	23 days
Third-party review	No

APPLICANT

Company	Kallestad Diag, A Div. of Erbamont, Inc.
Location	Chaska, MN, US
Contact	JAN NEBELSICK
510(k) history	58 submissions · 58 cleared · 1987-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883711/>, 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 29, 2026