

K851389 APO B RIA KITJul 10, 1985
92 days to decisionK851389 · Product code: **MSJ** · Immunology
Source: <https://www.510kdatabase.net/k851389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apolipoproteins (MSJ)
Date received	Apr 9, 1985
Decision date	Jul 10, 1985
Days to decision	92 days
Third-party review	No

APPLICANT

Company	Iso-Tex Diagnostics
Location	Walker, MI, US
Contact	EDWARD G EZRAILSON
510(k) history	3 submissions · 2 cleared · 1979-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k851389/>; 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 30, 2026