

K880254 SM ANTIBODY TEST KITApr 6, 1988
77 days to decisionK880254 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k880254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Jan 20, 1988
Decision date	Apr 6, 1988
Days to decision	77 days
Third-party review	No

APPLICANT

Company	Lipogen, Inc.
Location	Knoxville, TN, US
Contact	W FOUNTAIN
510(k) history	15 submissions · 15 cleared · 1987-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880254/>; 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