

K854083 XYLENE SUBSTITUTE MONTANTOct 22, 1985
15 days to decisionK854083 · Product code: **KEM** · Pathology
Source: <https://www.510kdatabase.net/k854083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Clearing (KEM)
Date received	Oct 7, 1985
Decision date	Oct 22, 1985
Days to decision	15 days
Third-party review	No

APPLICANT

Company	Lerner Laboratories, Inc.
Location	Mchenry, IL, US
Contact	SUSAN E SEGAL
510(k) history	5 submissions · 5 cleared · 1976-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854083/>; 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