

K942192 THEOPHYLLINE FPIA REAGENT SET AND CALIBRATORSJul 13, 1994
70 days to decisionK942192 · Product code: LER · Chemistry
Source: <https://www.510kdatabase.net/k942192/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Theophylline (LER)
Date received	May 4, 1994
Decision date	Jul 13, 1994
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	BARRY D ROBINS
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942192/> 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