

K894529 FPR THEOPHYLLINE KITSep 15, 1989
57 days to decisionK894529 · Product code: **LGS** · Toxicology
Source: <https://www.510kdatabase.net/k894529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Theophylline (LGS)
Date received	Jul 20, 1989
Decision date	Sep 15, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

Company	Colony Laboratories, Inc.
Location	Washington, DC, US
Contact	DALE B HINSON
510(k) history	16 submissions · 16 cleared · 1989-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894529/>; 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