

K961393 TRICYCLICS SERUM TOX ASSAYJun 12, 1996
62 days to decisionK961393 · Product code: **LFH** · Toxicology
Source: <https://www.510kdatabase.net/k961393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Spectrometry, Tricyclic Antidepressant Drugs (LFH)
Date received	Apr 11, 1996
Decision date	Jun 12, 1996
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YUH-GENG TSAY, PH.D.
510(k) history	66 submissions · 66 cleared · 1982-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961393/> 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 28, 2026