

**K983268 MODIFICATION OF TRICYCLIC SERUM TOX EIA
ASSAY**Nov 18, 1998
62 days to decisionK983268 · Product code: **LFH** · Toxicology
Source: <https://www.510kdatabase.net/k983268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Spectrometry, Tricyclic Antidepressant Drugs (LFH)
Date received	Sep 17, 1998
Decision date	Nov 18, 1998
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
510(k) history	66 submissions · 66 cleared · 1982-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983268/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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