

K213875 DRI TM Tricyclics Serum Tox AssayDec 21, 2022
373 days to decisionK213875 · Product code: **LFH** · Toxicology
Source: <https://www.510kdatabase.net/k213875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Spectrometry, Tricyclic Antidepressant Drugs (LFH)
Date received	Dec 13, 2021
Decision date	Dec 21, 2022
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microgenics Corporation
Location	Fremont Blvd., CA, US
Contact	Pranjali Shinde
510(k) history	21 submissions · 20 cleared · 2009-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213875/> 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