FDA 510(k) Premarket Notification

K213875 DRI TM Tricyclics Serum Tox Assay

CLEARED

Dec 21, 2022
373 days to decision

K213875 · 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