

K231020 Alinity c Tricyclic Antidepressants Reagent KitNov 17, 2023
221 days to decisionK231020 · Product code: **LFH** · Toxicology
Source: <https://www.510kdatabase.net/k231020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Spectrometry, Tricyclic Antidepressant Drugs (LFH)
Date received	Apr 10, 2023
Decision date	Nov 17, 2023
Days to decision	221 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

REGULATORY CONSULTANT

Consulting firm	Thermo Fisher Scientific
Contact	Pranjali Shinde

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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