

K243498 Alinity c Benzodiazepines Reagent KitDec 11, 2024
29 days to decisionK243498 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k243498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Nov 12, 2024
Decision date	Dec 11, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243498/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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