

K190968 CEDIA Benzodiazepine AssayDec 9, 2019
241 days to decisionK190968 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k190968/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Apr 12, 2019
Decision date	Dec 9, 2019
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190968/> 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