

K231007 CEDIA Heroin Metabolite (6-AM) AssaySep 27, 2023
173 days to decisionK231007 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k231007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 7, 2023
Decision date	Sep 27, 2023
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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