

K192943 CEDIA Heroin Metabolite (6-AM) assay

Dec 16, 2019
59 days to decision

K192943 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k192943/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 18, 2019
Decision date	Dec 16, 2019
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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