

K173195 DRI Hydrocodone AssayFeb 13, 2018
134 days to decisionK173195 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k173195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 2, 2017
Decision date	Feb 13, 2018
Days to decision	134 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/k173195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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