

K163101 CEDIA Buprenorphine II AssayApr 6, 2017
150 days to decisionK163101 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k163101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Nov 7, 2016
Decision date	Apr 6, 2017
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CEDIA Buprenorphine II Calibrators; CEDIA Negative Calibrator II; CEDIA Buprenorphine II Control Set

APPLICANT

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

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