

K152643 EGENS Urine Test Cup THC-MDMA, EGENS Urine Test DipCard THC-MDMA, EGENS Urine Test Cassette MarijuanaNov 2, 2015
48 days to decisionK152643 · Product code: LDJ · Toxicology
Source: <https://www.510kdatabase.net/k152643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Sep 15, 2015
Decision date	Nov 2, 2015
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nantong Egens Biotech Co., Ltd.
Location	Nantong, CN
Contact	Yan Cao
510(k) history	2 submissions · 2 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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