

K153741 CLUNGENE Methamphetamine Test, CLUNGENE Morphine Test, CLUNGENE Marijuana Test

Mar 18, 2016
81 days to decision

K153741 · Product code: LDJ · Toxicology
Source: <https://www.510kdatabase.net/k153741/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Dec 28, 2015
Decision date	Mar 18, 2016
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Clongene Biotech Co., Ltd.
Location	Hangzhou, CN
Contact	ZHENG SHUJIAN
510(k) history	9 submissions · 9 cleared · 2016-2026

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k153741/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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