

**K190412 CLUNGENE Multi-Drug Test Dip Card, CLUNGENE Multi-Drug Test Easy Cup**Mar 21, 2019  
28 days to decisionK190412 · Product code: **NGL** · Toxicology  
Source: <https://www.510kdatabase.net/k190412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Feb 21, 2019
Decision date	Mar 21, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Clongene Biotech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Zheng Shujian
510(k) history	9 submissions · 9 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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