

K180255 CLUNGENE Multi-Drug Test Dip Card, CLUNGENE Multi-Drug Test Easy CupFeb 28, 2018
29 days to decisionK180255 · Product code: PTH · Toxicology
Source: <https://www.510kdatabase.net/k180255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Barbiturate, Over The Counter (PTH)
Date received	Jan 30, 2018
Decision date	Feb 28, 2018
Days to decision	29 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.netDevice record: <https://www.510kdatabase.net/k180255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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