

K161044 AssureTech Methamphetamine Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup), AssureTech Phencyclidine Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup), AssureTech Marijuana Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)Jul 6, 2016
84 days to decisionK161044 · Product code: **DJC** · Toxicology
Source: <https://www.510kdatabase.net/k161044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thin Layer Chromatography, Methamphetamine (DJC)
Date received	Apr 13, 2016
Decision date	Jul 6, 2016
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Assure Tech. (Hangzhou) Co, Ltd.
Location	Hangzhou, CN
Contact	SHISHENG LING
510(k) history	7 submissions · 7 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161044/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026