

K153465 AssureTech Amphetamine Tests (Strip, Dip Card, Quick Cup, Turn-Key Split Cup), AssureTech Cocaine Tests (Strip, Dip Card, Quick Cup, Turn-Key Split Cup), AssureTech Morphine Tests (Strip, Dip Card, Quick Cup, Turn-Key Split Cup)

Mar 31, 2016
121 days to decision

K153465 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k153465/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 1, 2015
Decision date	Mar 31, 2016
Days to decision	121 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.net

Device record: <https://www.510kdatabase.net/k153465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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