

K180878 BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use, BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx

Dec 17, 2018
258 days to decision

K180878 · Product code: DJC · Toxicology
Source: <https://www.510kdatabase.net/k180878/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thin Layer Chromatography, Methamphetamine (DJC)
Date received	Apr 3, 2018
Decision date	Dec 17, 2018
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Venture Bio-Tech Co., Ltd.
Location	Shanghai, CN
Contact	Longli Long
510(k) history	2 submissions · 2 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Shanghai Thinkwell Consulting Co., Ltd.
Contact	Ethan Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)