

K180879 BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use

Dec 14, 2018
255 days to decision

K180879 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k180879/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Apr 3, 2018
Decision date	Dec 14, 2018
Days to decision	255 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)
