FDA 510(k) Premarket Notification

CLEARED

K233019 AllTest Multi-Drug Rapid Test Cup

Dec 13, 2023
82 days to decision

K233019 · Product code: **DKZ** · Toxicology
Source: https://www.510kdatabase.net/k233019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Sep 22, 2023
Decision date	Dec 13, 2023
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AllTest Multi-Drug Rapid Test Panel; AllTest Multi-Drug Rapid Test Cup Rx; AllTest Multi-Drug Rapid Test Panel Rx

APPLICANT

Company	**Hangzhou AllTest Biotech Co., Ltd.**
Location	Hangzhou, CN
Contact	Rosa Wu
510(k) history	14 submissions · 14 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**LSI International, Inc.**
Contact	Joe Shia

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