

K141532 CR3 KEYLESS SPLIT SAMPLE CUP AMPHETAMINE-COCAINEJul 14, 2014
34 days to decisionK141532 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k141532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jun 10, 2014
Decision date	Jul 14, 2014
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Joe Shia
510(k) history	43 submissions · 43 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141532/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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