FDA 510(k) Premarket Notification

CLEARED

K122904 WONDFO MULTI-DRUG URINE TEST CUP MODEL W2002-CU

Nov 15, 2012
55 days to decision

K122904 · Product code: **DKZ** · Toxicology
Source: https://www.510kdatabase.net/k122904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Sep 21, 2012
Decision date	Nov 15, 2012
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary
Other names	W2003-CU; W2004-CU; W2005-CU; W2006-CU; W2007-CU; W2008-CU; W2009-CU;

APPLICANT

Company	**Guangzhou Wondfo Biotech Co., Ltd.**
Location	Yardley, PA, US
Contact	Joe Shia
Website	https://www.wondfo.com.cn
510(k) history	43 submissions · 43 cleared · 2005-2026

Guangzhou Wondfo Biotech Co., Ltd. is a leading in vitro diagnostic (IVD) company founded in 1992. The company specializes in rapid point-of-care testing (POCT) devices and reagents. Wondfo operates with a manufacturing facility in Yardley, US, and serves over 150 countries globally. Wondfo has received FDA 510(k) clearances from total submissions since 2005. The company's regulatory portfolio is dominated by toxicology devices, including multi-drug urine test panels, cups, and dipsticks for substance screening. The latest clearance was in 2026, confirming active regulato...