FDA 510(k) Premarket Notification

K072500 ONE STEP HCG URINE/SERUM TEST

CLEARED

Apr 21, 2009
594 days to decision

K072500 · Product code: **DHA** · Chemistry
Source: https://www.510kdatabase.net/k072500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Sep 5, 2007
Decision date	Apr 21, 2009
Days to decision	594 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guangzhou Wondfo Biotech Co., Ltd.**
Location	Yardley, PA, US
Contact	HOWARD MANN
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...