

**K112395 WONDFO PHENCYCLIDINE URINE TEST, TRICYCLIC
ANTIDEPRESSANTS URINE TEST**Sep 9, 2011
21 days to decisionK112395 · Product code: **LFG** · Toxicology
Source: <https://www.510kdatabase.net/k112395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Tricyclic Antidepressant Drugs (LFG)
Date received	Aug 19, 2011
Decision date	Sep 9, 2011
Days to decision	21 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

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