

K143535 CR3 Keyless Split Sample Cup Secobarbital-MethadoneJan 13, 2015
29 days to decisionK143535 · Product code: **DIS** · Chemistry
Source: <https://www.510kdatabase.net/k143535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Dec 15, 2014
Decision date	Jan 13, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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