

K151478 Wondfo CR3 Keyless Split Sample CupJul 1, 2015
29 days to decisionK151478 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k151478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 2, 2015
Decision date	Jul 1, 2015
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	JOE SHIA

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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