

K140089 CR3 KEYLESS SPLIT SAMPLE CUP(OPI-BZO)Apr 8, 2014
84 days to decisionK140089 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k140089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jan 14, 2014
Decision date	Apr 8, 2014
Days to decision	84 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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