FDA 510(k) Premarket Notification

CLEARED

K150179 CR3 Keyless Split Sample Cup Oxycodone - Cannabinoids

Feb 25, 2015
29 days to decision

K150179 · Product code: **DJG** · Toxicology
Source: https://www.510kdatabase.net/k150179/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jan 27, 2015
Decision date	Feb 25, 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