

K152025 AssureTech Buprenorphine Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup), AssureTech Methadone Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)

Oct 5, 2015
75 days to decision

K152025 · Product code: **DJR** · Chemistry
Source: <https://www.510kdatabase.net/k152025/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Jul 22, 2015
Decision date	Oct 5, 2015
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Assure Tech. Co., Ltd.
Location	Hangzhou, CN
Contact	ERIC LIN
510(k) history	3 submissions · 3 cleared · 2015-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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